PRECLINICAL AND COMPARATIVE CLINICAL STUDY OF MARUTHAMPATTAI KUDINEER AND YOGAM THERAPY IN THE MANAGEMENT OF MADHUMEGAM (TYPE II DIABETES)

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DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled "Preclinical and comparative clinical study of *Maruthampattai kudineer* and *yogam* therapy in the management of madhumegam (Type II diabetes is a bonafide and genuine research work carried out by me under the guidance of **Dr.Dr.N.J.Muthukumar MD(S)**,Associate professor, Head of the department (i/c) Department of Sirappu Maruthuvam, National Institute of Siddha, Chennai -47, and the dissertation has not formed the basis for the award of any Degree, Diploma, Fellowship or other similar title.

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BONAFIDE CERTIFICATE

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INTRODUCTION

AIM AND OBJECTIVES

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INTRODUCTION

The siddha system represents the antiquity of ancient medicinal tradition prevalent in the Indian sub-continent. The immortal siddha masters describe ‘health’ as the harmonious equilibrium in the three main functionalities in the human body.

-the balanced functioning of the three Thodams in the body

-the function of the seven thathus or tissues that constitute the formation of the body; and the resultant of their functions

-the balanced functioning of the elimination system; the malam

Man is nothing but a world in miniature containing the five elements and all the various principles mentioned in siddha system.

Siddha system of medicine is a science which gives ailments to body and mind. Life style advocacies, selection of functional foods and person oriented treatment regimen are the uniqueness of Siddha system of medicine.

Siddhars are the one who attained perfection in yogic practices to ultimately reach the stage of immortality. Through higher- level yogic practices they attained a state of ultra-luminosity that results in invisibility; thus they remained impervious to ordinary vision. Such Siddhars worked incessantly for the propagation of knowledge and the evolution of souls.

According to Siddha system of Medicine, diseases are classified into 4448 in number. Yugi classified 20 types of *Pramegam* into 3 categories. Four types under *vatham*, six under *pitham t*en under *kabam*. *Madhumegam* comes under *pitham* category.

Madhumegam is also called as "*Neerizhivu*" characterised by increased and frequent passing of urine, which is sweet in odour, resulting in gradual diminution of *udalthathukkal* .

The clinical features of *madhumegam* can be correlated with type 2diabetes mellitus in modern science.

The term “Diabetes mellitus” is a clinical syndrome characterised by an increase in plasma blood glucose. Diabetes has many causes but is commonly due to type 1 and type 2diabetes. Type 1 diabetes is caused by autoimmune destruction of insulin producing cells in the pancreas, resulting in absolute insulin deficiency, whereas type 2 diabetes is characterised by resistance to the action of insulin and an inability to produce sufficient insulin to overcome this insulin resistance.

The first WHO *Global report on diabetes* demonstrates that the number of adults living with diabetes has almost quadrupled since 1980 to 422 million adults. This dramatic rise is largely due to the rise in type 2 diabetes and factors driving it include overweight and obesity. In 2012 alone diabetes caused 1.5 million deaths.

According to statistics from the International Diabetes Federation (IDF), India has more diabetics than any other nation of the world. Current estimates peg the number of diabetics in the country at about 62 million – an increase of over 10 million from 2011 when estimates suggested that about 50.8 million people in the country were suffering from the disease. By the year 2030, over 100 million people in India are likely to suffer from diabetes.

Yogam is a precious art contributed to the siddha system of medicine. *Yogam* is one of the kayalkalpam methods that preserve physical and mental health problems.The qualitative well-being is something that yoga and other Indian systems of medicine have considered important for thousands of years.*Yogam* has become the 13th intangible cultural heritage that has been listed from India so far with UNESCO. The Indian government is capitalizing on yoga’s popularity by supporting global events such as the International Day of Yoga that make the practice even more susceptible to global and commercial forces. Thus it is gaining awareness and importance among the people.

Nowadays sedentary life style of the people have lead many metabolic disorders and one among such disease with a large epidemiology is “*Madhumegam”*.So I have chosen to conduct my study on *Yogam* in the management of *Madhumegam* along with the trial drug *Marutham pattai* kudineer. The In-vitro &In-vivo studies of most of the ingredients like *Syzygium cumini*, *Strychnos potatorum*, Triphala, *Terminalia arjuna*shows potent anti-diabetic activity.

The currently available oral anti-hyperglycaemic agents for clinical use have characteristic profile of side effects, drug dependency and drug resistance in other systems. The management of Diabetes with agents devoid of any side effects is still a challenge to the health care sector.Hence, in recent times there has been an intense search for drugless measures not only to control DM, but also to prevent its complications .Therefore a cost effective and an integrated management is the need of the hour.Yoga practice has a behavioural activation component which enhances and also preserves physical fitness, coordination and flexibility, while preventing or minimizing deterioration. Hence, yoga has special significance in the case of progressive metabolic disorders such as Diabetes.

The author is obliged to conduct this study to provide a holistic approach through *yogam* based life style changes in diabetic patients.

Aim:

To evaluate the effectiveness of *Yogam Therapy*and *Marutham Pattai Kudineer* for the management of *"Madhumegam* "(Type II Diabetes Mellitus)

Primary Objective:

To study the effectiveness of yogam in the management of *Madhumegam*(Type II Diabetes Mellitus) .

Secondary objective :

- To examine the Siddha diagnostic methods such as Envagaithervu, Neerkkuri and Neikkuri in Madhumegam patients
- To evaluate the safety of the trial drugs by doing toxicological studies acute and chronic in animal models.
- Biochemical analysis of drug**.**

MADHUMEGAM

Siddha system of medicine is an ancient system and it deals not only with the body of man but also with the inner soul. The word *Siddha* comes from *Siddh*i which means an object to be attained. It generally refers to the *Astama Siddhi* i.e. the eight super natural powers.

Both Nature and Human body is made up of five elements (*Piruthivi, Appu, Theayu,Vaayu & Agaayam*) .Any adverse changes in the universe causes the same effect in man because what exists in universe exists in man also.

In Siddha system of medicine, diseases are classified into 4448 types. According to *Yugi vaithiya chinthaaman*i, *Meghanoi* is classified into 20 types. "*Madhumegam*" is one among them, which comes under *Pitha* (*Azhal*) type.

Definition – Madhumegam:

Madhumegam is a clinical condition characterized by frequent passage of urine more than the normal resulting in deterioration and diminution of seven thathus (*Saram, senner, oon, kozhuppu, enbu, moolai, and sukkilam*).

அண்மையா யடிக் கடிக்கு நீரிறங்கு
முடிக்கடிக்கு அரை நாழி தனிலே காணும்
வெண்மையான னடினதனிற்றான் பிடிக்கும்
மிக்கான சடம் வெளுத்து மேனி கண்ணும்
-யூகி வைத்திய சிந்தாமணி.

சரியாக மேகத்தா லபான வாயு
தான்புகைக்கு மேலேறிக் கபாலச் சூடாம்
பேரிதான மேகத்தா லத்தி வெந்து
போமப்பா தசைவெந்து ரத்தம் வற்றிப்
பரிவாகித் தசவாயவால் மந்தங் கொண்டு
பெருந்தீனி மலபந்தம் உதான வாயு
வரிவாக தேகமெலாம் விட நீராலே
மெய்யழிந்த மேகமென்ற திருப தாச்சே.
சித்தர் நாடி நூல்

Synonyms of Madhumegam;

According to *Siddha Maruthuvam*, the synonyms of Madhumegam are "*Inippuneer*" and "*Neerizhivu*."

Etiology:

The authentic etiological factors described by various siddhars are as follows:

கோதையர் கலவி போதைகொழுத்தமீ னிறைச்சி போதைப்
பாதுவாய் நெய்யும் பாலும் பரிவுட னுண்ப ராகில்
சோதபாண் டுருவ மிக்க சுக்கில பிரமே கந்தான்
ஓதுநீ ரிழிவு சேர வுண்டென வறிந்து கொள்ளே.

-அகத்தியர் 1200

The above poem quotes that excessive intake of Ghee, Milk, Fish, toddy and excessive indulgence in sex leads to Madhumegam, Excessive body heat (Azhal) and excessive hunger also leads to Madhumegam.

Pshycosomatic factors:

Yugimunivar and other siddhars stress a great importance to Pshycosomatic factor. All antisocial activities ultimately result in subjective guiltiness and pshycosomatic stress resulting in diseases like Diabetes, Peptic ulcer and Hypertension.

இயம்பவே ஆறுகுணம் பின்னஞ் செய்தல்
ஆயம்வே ஆலயத்திற் சலம்விட் டோர்க்கு
ஆதியாம்வேதத்தை த்தூஷிற் தோர்க்கும்
சுருக்காக மேகம்வந் துற்ப விக்குந் தானே
யூகி வைத்திய சிந்தாமணி.

Noi Enn (Classification):

Twenty varieties of Megha disorders have been discussed by Yugimuni, Agathiyar and Threaiyar.

Yugimuni classified Megha disorder into 20 types. Among this Vatha 4, Pitta 6 and Kabha 10types.

In Siddha text like *Thirumoolar vaidiyam 600*,*Prameham* is also called as *Neerizhivu*. In *Agasthiya*r texts and *"Yugimuni Vaidiya Chinthamani* 800", *Madhumegam* is one among the 20 varieties of *Prameham*. Each author who have dealt *megha* disorders have differently classified them under three *thosam* and have given names according to their concept. But the number, signs and symptoms of the classified disorders are almost identical in the description of the disease.

Classification:

1) Classification of Prameham according toYugimuni Vaidiya chinthamani 800 as follows:

Types under vatha:

1. Nei mana neer
2. Pasu mana neer
3. Oon mana neer
4. Seel mana neer

Types under Pitta

1. Yanai kozhuppu mana neer
2. Katralai mana neer
3. Chunna mana neer
4. Inippu megam
5. Palingu neer
6. Muyarkuruthi neer

Types under kabha

1. Vasa neer
2. Theli neer
3. Moolai urukku neer
4. Ilaneer neer
5. Kal neer
6. Sukkila neer
7. Thean neer
8. Uppu neer
9. Kalu neer
10. Iraichi neer

Noi kuri kunangal (Clinical features):

Yugimuni has described the signs and symptoms of Madhumegam are passing of urine in large quantity at regular intervals, while passing urine the patient experiences burning and spasmodic pain in the urethra and dull pain in the testis.

The urine thus passed is cold, slimy to touch, has brownish yellow in colour produces white sediments which adhere to the bottom of the vessel in which it is collected. The skin is pale and there is generalized tenderness. If it is not diagnosed in time and not initiated proper treatment with diet restriction, the disease will run a fulminating course resulting in death within five years of periods.

Avaithaigal (Complications of Madhumegam):

காணவே முதலவத்தைச் சரீரந் தானுங்
கனமாக பருத்திறுகி நீர்த்து வாரம்
வேணவே வேண்டாக்கி யகலம் பண்ணு
மிக்கவிரண் டாமவத்தை விளம்ப கேளாய்
மூணவே மூத்திரப்பீ டையுமாச் சுக்ல
முகமுழுகித் தேஜசுதான் மிகவே குன்றும்
நாணவே மூன்றாகு மவத்தைக் குத்தான்
நாவறளும் வாயுவது மீறுந் தானே

தாறான நாலவத்தை யங்க தாகுஞ்
சன்னியது பாதமுண்டா மைந்த வத்தைத்
தேறான நீர்ப் பெருகுந் தாது நஷ்டம்
நிலையாளு மவத்தையுடற் கிடைகொள் ளாது
முனான முர்ச்சைவரு மேழ வத்தை
மிக்கவரோ சகஞ்சுவாசந் தேக சாட்டியம்
ஏனான எட்டாவ தவத்தை தானே
எழுகிரத்தி பிளவை யுந்தான் மிகவுண் டாமே

உண்டாகு மொன்பதா மவத்தை கேளாய்
ஒழுக்கான வாசாரங் கிருமி யுண்டாம்
பண்டான பத்தாந்த னவத்தைக் கேளாய்
பாரமாம் சயங்கண்டு பரத்திக் கேகும்
வெண்டாகு மேகந்தா னிருப துக்கும்
விளக்கியதோர் தசவத்தை விவரஞ் சொன்னோம்.

Siddhar Yugimuni has described the complications of *Madhumegam* as "*Avaithaigal*". There are ten avaithaigal described one by one as follows:

1. Obesity and dilation of urethral orifice
2. Body becomes dry and loses its lustre .Urinary disorders.
3. Dryness of the tongue and distension of the abdomen due flatulence.
4. Delirium (Toxic condition) supervenes following dehydration due to excessive elimination of tissue fluid.
5. Restlessness due to loss of vital fluid in urine
6. Unconsciousness and restlessness.
7. Nausea, tastelessness, dyspnoea, exhaustion.
8. Carbuncle and multiple abscess formation
9. Maggot formation and generalized emaciation.
10. Cough with profuse expectoration leading to death.

Mukkutra Verupaadugal (Pathology of Madhumegam):

The whole ancient medicine is based upon the '*Thridosham* theory'. Due to intrinsic and extrinsic factors, the *pitha(Azhal*) in the body gets altered. This is followed by the derangement of metabolic energy caused by the involvement of *vatha(Vali).* Finally, the function of *vatha(Vali)* and *kabam(Iyam*) also altered resulting in dearrangement of normal structure and functions of the seven thathus.

Udal Kattugal:

These are seven basic principles which constitute the entire body. There are seven Udal kattugal described in Siddha text.

SEVEN PHYSICAL CONSTITUENTS OF THE BODY

1. Saaram - This gives mental and physical perseverance.
2. Senneer - Imparts colour to the body and nourishes the body
3. Oon - It gives shape to the body according to the physical activity and covers the bone.
4. Kozhuppu - It lubricates the joints and other parts of the body for smooth functioning.
5. Enbu - Supports the frame and responsible for the postures and movements of the body.
6. Moolai - It occupies the medulla of the bones and gives strength and softness to them.
7. Sukkilam - It is responsible for reproduction

VARIATIONS OF THE PHYSICAL CONSTITUENTS

UDAL THATHUKKAAL	INCREASED FEATURES	DECREASED FEATURES
SARAM	Leads to a disease identical to the increase in kabam like loss of appetite,indigestion etc..	Dryness of skin, tiredness, diminished activity of sense organs, loss of weight, lassitude
SENNEER	Boils in different parts of the body, jaundice, haematuria, colic pain,anorexia	Pallor of the body, Tiredness, lassitude, cold, anaemia
OON	Hypermuscular around the neck, cheeks, vernical ulcer tumour in abdomen, thigh and genitalia.	Impairment of sense organs, joints, jaws, thigh and genitalia gets shortened.
KOZHUPPU	Identical feature of increased oon, associated with dyspnoea on exertion,	Pain in the hip region, spleenomegaly and emaciation.
ENBU	Growth of bones and teeth.	Bone diseases, loosening of teeth and nails, splitting and falling of hair.
MOOLAI	Heaviness of the body and eyes, swollen inter phalangeal joints, oliguria and non-healing ulcers.	Osteoporosis &Blurred vision.
SUKKILAM (OR) SURONITHAM	Increased sexual activity, urinary calculi.	Pain in the genitalia, failure to reproduction

In case of Madhumegam, all seven thathus are affected.

1. Saram - Tiredness
2. Senneer - Reduced strength
3. Oon - Weight loss
4. Kozhupppu - Weight loss or Obese
5. Enbu - Joint pain
6. Moolai - Bone Marrow Affected
7. Sukkilam - Body becomes dry and loses its lusture

Piniyari muraimai:

Piniyari muraimai is the method of diagnosing the disease affecting the people. It is based upon the following aspects:

1. Poriyalarithal
2. Pulanaalarithal
3. Vinaathal
4. Envagaithervugal
5. Naadiparitchai

The above principles correspond to the methodology of inspection, palpation and interrogation of modern medicine.

Poriyalarithal and Pulanalarithal:

Iympori is considered as the five sense organs namely Nose, Tongue, Eye, Skin and Ear.While Iympulan is considered as the five sense of perception. They are smell, Taste, Vision, touch and sound. Physician's pori and pulan are used as the tools for examining the pori, pulan of the patient.

Envagai thervugal:

Eight different kinds of tests to be applied or attended by a physician before arriving a correct diagnosis. These are also called Attavitha Paritchai or Attasthanna Parikshai.

Envagai thervugal is considered as physician's Instrument. There are,

1. Naadi (Pulse)
2. Sparisam (Palpation)
3. Naa (Tongue examination)
4. Niram (Colour of the body)
5. Mozhi (Speech)
6. Vizhi (Eye Examination)
7. Malam (Motion Examination)
8. Moothiram (Urine examination)

Therefore, to arrive at the diagnosis for any disease, it is imperative to apply the Envagai thervugal.

"தொகுக்கலுற்று அட்டவித பரீட்சை தன்னை
குலுக்கமுலறும் பண்டிாரே தெளிவாகப்
பகுக்கறிய நாடியை நீ பிடித்தப் பாரு
பகர்கின்ற வார்த்தையை பார் நாவைப் பாரு
வகுக்கறிய தேகமதை தொட்டுப்பாரு
வளமான சரீரத்தின் நிறக்தைப் பாரு
சகிக்கரிய மலத்தைப்பார் சலத்தைப் பார
சார்ந்த விழி தனைப்பார்த்து தெளிவாய்க் கானே"

அகத்தியர் வல்லாதி 600

1. Naadi (Pulse):

Naadi is the vital force.Any change in the three doshas are best diagnosed by feeling the naadi. Naadi is an important observation for diagnosis and prognosis.Naadi is responsible for the existence of life and can be felt one inch below the wrist on the radial side by means of palapation with the tips of index, middle and ring finger corresponding to Vatham ,Ptham and Kabam.

2. Sparisam: (Palpation):

The following points are elicited by Sparisam , the temperature of skin (Heat or cold) , smoothness, roughness, softness, sweat , dryness , sensation .

3. Naa:

Colour, coating, ulcer, deviation, roughness, silky soft & any abnormality of the tongue,

4. Niram:

Colour of skin, palm etc.

5. Mozhi:

Mode & quality of Speech,

6. Vizhi:

Colour, vision,dryness, itching, cataract and any abnormality

7. Malam Faeces):

In the examination of Malam, Niram (colour) ,Nurai (froth), Erugal (Solid).,Elagal (Semisolid or liquid), quantity (increased or decreased) smell can be noted other examination like diarrhea, presence of blood, mucus, undigested matter in the stools and odour can also be studied.

8. Moothiram: (Urine)

In the examinantion of urine, colour, odour, quantity of urine, the presence of froth, deposits,blood, pus, inorganic sediments, abnormal constituents such as sugar, protein etc… and the frequency of micturitions are to be noted.

The diagnosis is usually arrived at by methods of urine examinations called

i. Neerkuri
ii. Neikuru

i)Neerkuri

In Neerkuri, Niram, Edai, Manam, Nurai and Enjal of the urine voided is noted. This has been already mentioned in Envagai thervugal.

The following parameters in the urine should be examined.

Niram **:** It indicates the colour of the urine voided.

Edai **:** It indicates the specific gravity of urine (increased or decreased quantity)

Manam **:** It indicates the smell of urine voided.

Nurai **:** It indicates the frothy nature of urine voided

Enjal **:** It indicates the quantity of urine

Neerkuri of Madhumegam is studied as follows:

Niram **:** Clear and white.This is due to kabha vitiation and it is not amenable to treatment.

Edai **:** Urine is thick

Manam **:** Smells like honey.

Nurai **:** It is frothy at the time of urination.

Enjal **:** Large quantity of urine is passed. This will result in the loss of large volume of water and life sustaining minerals resulting in Fatigue, exhaustion and weakness.

Neikuri:

A drop of Gingelly oil is dropped into a wide mouthed vessel containing the urine to be tested and kept it under the sunlight in a air free place. The variations of the three thathus in disease can be diagnosed by the behaviour of Gingelly oil on the surface of urine.

The drop of oil lengthening like a snake indicates Vatham (Vali)

The drop of oil spreading like a ring it indicates Pitham (Azhal)

If the oil drops assumes a pearl shape it is presumed to be Kabham(Iyam).

By the careful examination of the urine with gingelly oil, the physicians can know whether the disease is curable or not. For this purpose Siddhars have explained various spreading tendencies of oil on urine surface to define the prognosis of the disease.

Maruthuvam (treatment)

வைத்தியச் செயல் வைத்தியாமாமே
பலவாறு மாறுதலடைந்து கெடுக்கின்ற உடலை நிலைக்கும்படி
மாறுதல் அணுகாமலும் ஒரே தன்மையாக
செய்தும் அதனாலாஞ் செயிலக் குறைவின்றி
நடக்கச் செய்வது தெதுவோ அதுவே வைத்தியம்

-திருமூலர்800

Siddha system of medicine besides treating the diseases and improves the body condition. This is said as follows:

a.Neekkam (Treatment)

b. Niraivu (Restoration)

c.Kaappu (Prevention

Neekkam (Treatment)

The three uyir thathus which are responsible for organization, regularization and integration of the bodily structures and their physiological functions are always kept in a state of equilibrium by word, thought, deed and food of the individual. The general aetiological factors for constitutional discomfort is said to be incompatible diet, mental and physical activities.

So, it is essential to know the disease and the cause for the onset of the disease, before treating the patient. The nature of the patient, the severity of illness, the season and time of the occurrence of the diseases must be observed

Niraivu (Restoration)

Patients' needs good discussion, motivation and persuasion to accept the eventuality of Diabetes and prepare for a lifestyle that provides optimization of metabolic status. Suitable and effective medicinal preparations have to be administered in the beginning itself to neutralize and eliminate the damage in the body tissues.

Siddhars aimed at bringing the three *thosam* in equilibrium in the treatment of disease. The treatment regimen has been constituted from plant to metal and mineral kingdoms.

Kaappu (Prevention)

Siddha system prominently projects the prevention of diseases by the following methods

1. Maintaining equilibrium of the three humours, is done by adopting *noiilla neri* technique emphasized by siddhar *Theraiyar*such as doing *vaanthi*(vomiting) in six months once, *paeth*i (purgation) every four months once, *nasiyam*(nasal drops) 45 days once and take oil bath weekly twice

2. Avoiding stress and strain by doing *Yogam* technique

3. Maintaining good mental health by doing meditation

Diet and Advices:

Type	Eat	Avoid
Vegetables	Brinjal, Broad beans, Bitterguard, Lady's finger, Cluster beans, Onion, Turnip, Cauliflower, White pumpkin, Cabbage, Drumstick, Spadix of the Plaintain, Cucumber, Beans, Green vegetables, Pulses	Unripe plaintain, Potato, Carrot, Beetroot, Elephant yam, Colachasia, Sweet pumpkin, Tubers, Tender coconut, Radish, Ground nut, Cashew nut
Fruits	Apple, Papaya ,Small Orange, Muskmelon , Pear, Guava	Dates, Jackfruit, Dried fruits, Banana, Tinned fruits, Apple, Sapota, Mango, Guava
Drinks	Coffee, Tea without sugar, Soda, Lime juice, Soup, Tomato juice,	Sugar items, Honey, Horlicks, Bournvita
Non vegetarian foods	Egg white	Dry fish, Meat, Chicken
Other foods	Tomato, Mint, Coriander, Onion, Sambar, Gingelly oil, Sesame, cotton seed, rice bran and safflower oils .Salt up to 6g/day is permitted. Restrict pickles, papad and salty processed foods,	Jaggery, Sugar candy, Badam, Cashew nut, Cake items, Ice cream, Betel, areca nut.

B.MODERN ASPECT

DIABETES MELLITUS

Diabetes mellitus:

Diabetes mellitus refers to a group of metabolic disorders that share the phenotype of hyperglycemia. Several distinct types of DM are caused by a complex interaction of genetics and environmental factors. Depending on the etiology of DM, factors contributing to hyperglycemia include reduced insulin secretion, decreased glucose utilization, and increased glucose production. The metabolic deregulation associated with DM causes secondary pathophysiologic changes in multiple organ system that impose a tremendous burden on the individual with diabetes and on the health care system.

Epidemiology:

The worldwide prevalence of DM has risen dramatically over the past two decades, from an estimated 30 million cases in 1985 to 382 million in 2013. Based on current trends the International Diabetes Federation projects that 592 million individuals will have diabetes by the year of 2035. Although the prevalence of type 1 and 2 DM is increasing worldwide, the prevalence of type 2 DM is rising much more rapidly because of increasing obesity, reduced activity levels. The countries with the greatest number of individuals with diabetes in 2013 are china (98.4 million), India (65.1 million), United states (24.2 million).The prevalence of diabetes according to WHO criteria was 5.6% and 2.7% among urban and rural areas respectively.

Classification:

There are two broad categories of DM, designated

Type 1 / IDDM (complete or near total insulin deficiency)

Type 2 / NIDDM (variable degrees of insulin resistance, impaired insulin secretion, increased glucose production)

Etiologic classification:

1.Type 1 / IDDM (complete or near total insulin deficiency)

A. immune mediated

B. idiopathic

2.Type 2 / NIDDM (variable degrees of insulin resistance, impaired insulin secretion, increased glucose production)

3. Other specific types:

A. Genetic defect of beta cell development or function:

B. Genetic defect in insulin action

C. Disease of exocrine pancreas

D. Endocrinopathies

F. Drug or chemical induced

G. Uncommon forms of immune mediated diabetes

4. Gestational diabetes mellitus

Risk factors for type 2 Diabetes mellitus:

Family history of diabetes

Obesity (BMI>25kg/m^2)

Physical inactivity

Race / ethnicity

Previously identified with IFG, IGT or hemoglobin A_{1c} of 5.7-6.4%

History of GDM or delivery of baby >4kg

Hypertension

HDL cholesterol level < 35mg/dl and TGL level > 250 mg/dl

Polycystic ovary syndrome

History of cardio vascular disease

Anatomy of the pancreas:

Pancreas is a retro-peritoneal, fleshy organ, has both endo and exocrine function. It is supra-umbilical, intrahepatic, posterio-abdominal, retroperitoneal organ, crossing the mid-line from right to the left. As it's retroperitoneal, the organ does not move with respiration.

Generally, it has head, neck, body and tail. The head of the pancreas is within the concavity of the duodenum. The neck crosses the portal vein. The body crosses the great vessels of the abdomen like, inferior vena cava, aorta, and left renal blood vessels. The tail of the pancreas is in the left hypochondrium and, it contacts the hilum of the spleen. The superior border is related to splenic artery.

The anterior border gives attachment of transverse mesocolon, this is a compound tubular gland showing endo and exocrine functions of which are correlated with pituitary gland.

Microscopic anatomy of islets of – Langerhans

They are found more in the tail of the pancreas than in the other parts. They form about 1 – 2% of pancreatic weight. There are about 2 millions of islets in human pancreas. Each islet has an epithelial mass, tunneled by labyrinthine capillaries. The position of the islets is mostly within the lobules, rather than between them. Each spheroid islet is surrounded by reticular membrane. Islet tissue is arranged in irregular anastomosing cellular plates. Their epithelial cords are separated by blood vessels. A sphincter controls the blood supply. The histological structure of the islets shows Alpha, Beta and Delta cells, of which,

Alpha cells form 20% and **glucagon** secreting
Beta cells form about 75% and **insulin** secreting
Delta cells form about 5% and **gastrin** secreting

Beta cells are the source of insulin hormone. The cells are polyhedral, the nuclei are centrally or eccentrically placed, the cytoplasm is grannular, filled with prominent secretary vacuoles containing few ribosomes. The secretory granules show species variations. In man they are spherical or elongated crystalline body.

INSULIN BIOSYNTHESIS, SECRETION, AND ACTION:

Biosynthesis

Insulin is produced in the beta cells of the pancreatic islets. It is initially synthesized as a single-chain 86-amino-acid precursor polypeptide, preproinsulin. Subsequent proteolytic processing removes the amino terminal signal peptide, giving rise to proinsulin. Proinsulin is structurally related to insulin-like growth factors I and II, which bind weakly to the insulin receptor. Cleavage of an internal 31-residue fragment from proinsulin generates the C peptide and the A (21 amino acids) and B (30 amino acids) chains of insulin, which are connected by disulphide bonds.

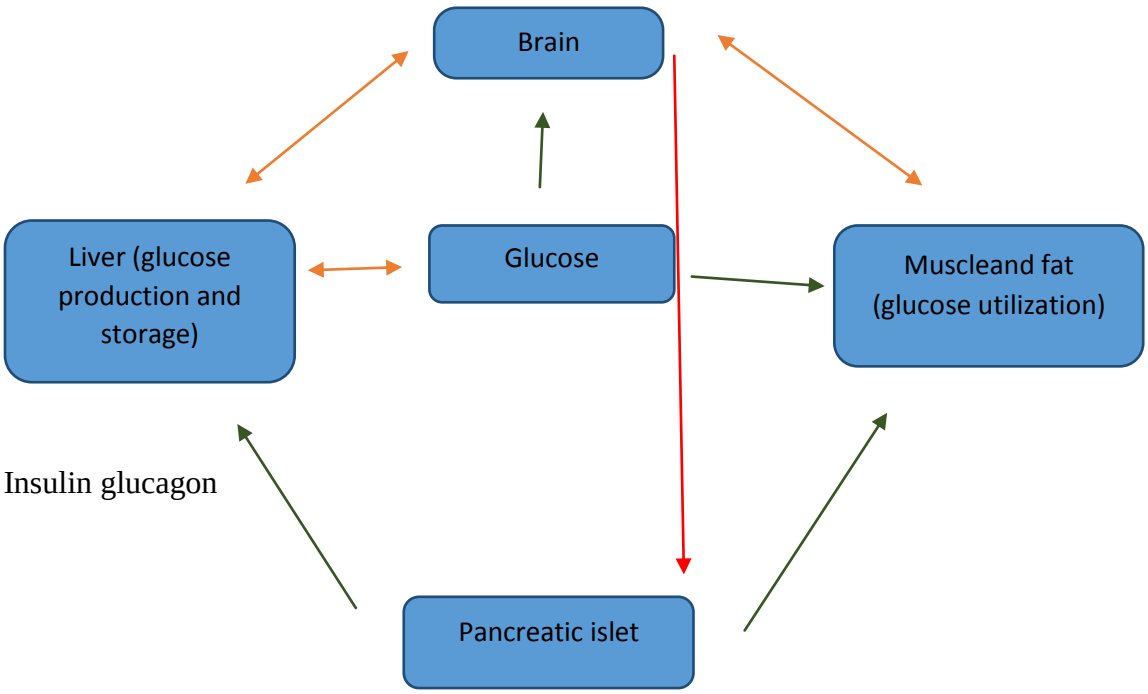
The mature insulin molecule and C peptide are stored together and co- secreted from secretory granules in the beta cells. Because the C peptide is less susceptible than insulin to hepatic degradation, it is a useful marker of insulin secretion and allows discrimination of endogenous and exogenous sources of insulin in the evaluation of hypoglycemia.

Human insulin is now produced by recombinant DNA technology; structural alterations at one or more residues are useful for modifying its physical and pharmacologic characteristics.

Secretion:

Glucose is the key regulator of insulin secretion by the pancreatic beta cell, although amino acids, ketones, various nutrients, gastrointestinal peptides, and neurotransmitters also influence insulin secretion. Glucose levels >3.9 mmol/L (70 mg/dL) stimulate insulin synthesis, primarily by enhancing protein translation and processing, as well as inducing insulin secretion. Glucose stimulates insulin secretion through a series of regulatory steps that begin with transport into the beta cell by the GLUT2 glucose transporter.

Glucose phosphorylation by glucokinase is the rate-limiting step that controls glucose-regulated insulin secretion.



Normal Blood Sugar Level

In normal persons, blood glucose level is controlled within a narrow range. After the overnight fasting, in early morning, the blood glucose level ranges between 80 and 90 mg/dl of blood. Between first and second hour after meals (post prandial), the blood glucose level raises to 120-140 mg/dl. The glucose level in the blood is brought back to normal at the end of second hour after the meals.

Necessity Of Regulation Of Blood Glucose Level

Regulation of blood glucose level is very essential because, glucose is the only nutrient that can be utilized by tissues of brain, retina and germinal epithelium of the gonads.

Role of Liver in the Maintenance of Blood Sugar Level

Liver acts as an important glucose buffer system. When blood glucose level increases after a meal, the excess glucose is converted into glycogen and stored in liver. Afterwards, when blood glucose level falls, the glycogen in liver is converted into glucose and released into the blood from the liver cells.

ROLE OF INSULIN IN THE MAINTENANCE OF BLOOD SUGAR LEVEL:

Insulin is the antidiabetic hormone, as it reduces blood sugar level. It reduces the blood sugar level by the following actions.

1. Transport and uptake of Glucose

When a food with excess amount of carbohydrate is taken, the blood sugar level is increased. Immediately, pancreas secretes insulin. The insulin facilitates the transport of glucose from the blood into the cells by increasing the permeability of cell membrane to glucose.

Insulin enhances the uptake of glucose by all the tissues particularly by liver, muscle and adipose tissues. However, insulin is not required for glucose uptake in some tissues like brain (except hypothalamus), renal tubules, mucus membrane of intestine and red blood cells.

2. Peripheral utilization of Glucose

The glucose entering the cells is oxidized by most of the cells immediately. The rate of utilization depends upon intake of glucose, and the glucose utilization is enhanced by insulin.

3.Storage of Glucose

Insulin promotes the rapid conversion of glucose into glycogen (glycogenesis) in muscle and liver. Thus, glucose is stored in these two organs in the form of glycogen. The insulin causes conversion of glucose into fatty acids.

4. Inhibition of Glycogenolysis

Insulin prevents the breakdown of glycogen into glucose in muscles and liver.

5. Inhibition of Gluconeogenesis

Insulin prevents gluconeogenesis i.e., it prevents the formation of glucose from proteins by following ways:

a.Inhibiting the release of amino acids from muscle and

b. Inhibiting the activities of enzymes involved in gluconeogenesis.

Thus insulin decreases the blood sugar level in following manner;

1. Facilitating the transport and uptake of glucose by the cells.
2. Increasing the peripheral utilization of glucose.
3. Conversion of glucose into glycogen in liver and muscle.
4. Prevention of glycogenolysis.
5. Inhibition of gluconeogenesis.

Role Of Glucagon In The Maintenance Of Blood Sugar Level

1. Glucagon increases glycogenolysis (breakdown of glycogen into glucose) in liver. And, the glucose thus formed is released from the liver cells into the blood. Glucagon does not induce glycogenolysis in muscle
2. Glucagon increases gluconeogenesis (formation of glucose from proteins) in liver. It promotes gluconeogenesis by:

   a. a.Activating the enzymes which convert pyruvate into phosphoenol and pyruvate
   b. b.Increasing the transport of amino acids into the liver cells. These amino acids are utilized for glucose formation.

TYPE 2 DM

(NON-INSULIN DEPENDENT DIABETES MELLITUS)

Pathophysiology:

Type 2 diabetes is due to insufficient insulin production from beta cells in the setting of insulin resistance. Insulin resistance, which is the inability of cells to respond adequately to normal levels of insulin, occurs primarily within the muscles, liver, and fat tissue.In the liver, insulin normally suppresses glucose release.

However, in the setting of insulin resistance, the liver inappropriately releases glucose into the blood. The proportion of insulin resistance versus beta cell dysfunction differs among individuals, with some having primarily insulin resistance and only a minor defect in insulin secretion and others with slight insulin resistance and primarily a lack of insulin secretion.

Other potentially important mechanisms associated with type 2 diabetes and insulin resistance include: increased breakdown of lipids within fat cells, resistance to and lack ofincretin, high glucagon levels in the blood, increased retention of salt and water by the

kidneys, and inappropriate regulation of metabolism by the central nervous system.However, not all people with insulin resistance develop diabetes, since an impairment of insulin secretion by pancreatic beta cells is also required.

Prevention:

Onset of type 2 diabetes can be delayed or prevented through proper nutrition and regular exercise. Intensive lifestyle measures may reduce the risk by over half. The benefit of exercise occurs regardless of the person's initial weight or subsequent weight loss. Evidence for the benefit of dietary changes alone, however, is limited,with some evidence for a diet high in green leafy vegetables and some for limiting the intake of sugary drinks.In those with impaired glucose tolerance, diet and exercise either alone or in combination with metformin or acarbose may decrease the risk of developing diabetes. Lifestyle interventions are more effective than metformin.

CLINICAL FEATURES OF DIABETES

The clinical features of the two main types of diabetes are compared below.

Comparative Clinical Features Of Type 1 And Type 2 Diabetes

	TYPE 1	**TYPE 2**
Age at onset	<40 years	>50 years
Duration of symptoms	Weeks	Months to years
Body weight	Normal or low	Obese
	TYPE 1	**TYPE 2**
Ketonuria	Yes	No
Rapid death without Treatment with insulin	Yes	No
Auto antibodies	Yes	No
Diabetic complications at diagnosis	No	25%
Family history of diabetes	Uncommon	Yes

The classical symptoms of thirst, polyuria, nocturia and rapid weight loss are prominent in type 1 diabetes, many of whom are asymptomatic or have non-specific complaints such as chronic fatigue and malaise.

Uncontrolled diabetes is associated with an increased, susceptibility to infection and patients may present with skin sepsis (boils) and genital candidiasis and complain of pruritus vulvae and balanitis.

Patients with type 1 diabetes often have no physical signs attributable to diabetes, but weight loss is common.

The physical signs in patients with type 2 diabetes at diagnosis depend on the mode of presentation. More than 70% are overweight, and obesity may be central (truncal or abdominal). Obesity is less common in developing countries.

Hypertension is present in 50% of patients with type 2 diabetes. Although hyperlipidaemia is also common, skin lesions such as xanthelasma and eruptive xanthomata are relatively rare.

Criteria for the diagnosis of Diabetes mellitus:

1. Symptoms of diabetes
2. Fasting / random / post prandial blood glucose concentration
3. HbA_{1c}
4. 2 hours plasma glucose during an oral glucose tolerance test

LABORATORY EVALUATION

If the patient is a known diabetic, the following tests are to be advised

- ✓ Fasting blood sugar (FBS)
- ✓ Postprandial blood sugar (PPBS)
- ✓ Glycated haemoglobin (HbA1c)
- ✓ Blood urea
- ✓ Serum creatinine
- ✓ Urine protein
- ✓ Haemogram
- ✓ Urine complete examination
- ✓ Lipids (total cholesterol, triglycerides, HDL, LDL)
- ✓ Liver function tests (LFT)

If the patient is not a known diabetic, the following tests can be advised

- ✓ Glucose tolerance test (GTT)
- ✓ Glycated haemoglobin (HbA1c)
- ✓ Blood urea
- ✓ Serum creatinine
- ✓ Urine P/C ratio
- ✓ Urine complete examination
- ✓ Lipids (total cholesterol, triglycerides, HDL, LDL)
- ✓ Liver function test(LFT)
- ✓ ECG

COMPLICATIONS OF DIABETES MELLITUS

1. Acute Complications

a. Diabetic ketoacidosis (DKA)

b. Nonketotic hyperosmolar state (NKHS)

c. Hyper osmolar coma hypoglycemia

Diabetic Ketoacidosis:

Diabetic ketoacidosis is a major medical emergency and remains a serious cause of morbidity, principally in people with type 1 diabetes. The average mortality in developed countries is 5-10% and is higher in the elderly.

A clear understanding of the biochemical basis and pathophysiology of this problem is essential for its efficient treatment.

Ketoacidosis is caused by insulin deficiency and an increase in catabolic hormones, leading to hepatic over-production of glucose and ketone bodies.

The cardinal biochemical features of diabetic ketoacidosis are:

a. hyperglycaemia

b. hyperketonaemia

c. metabolic acidosis.

Hyperglycaemia causes a profound osmotic diuresis leading to dehydration and electrolyte loss, particularly of sodium and potassium. The metabolic acidosis forces hydrogen ions into cells, displacing potassium ions, which may be lost in urine or through vomiting.

About half the deficit of total body water is derived from the intracellular compartment and occurs comparatively early in the development of acidosis with relatively few clinical features; the remainder represents loss of extra cellular fluid sustained largely in the later stages. It is at this time that marked contraction of the size of the extra cellular space occurs, with haemo concentration, a decreased blood volume, and finally a fall in blood pressure with associated renal ischaemia and oliguria.

Every patient in diabetic ketoacidosis is potassium-depleted, but the plasma concentration of potassium gives very little indication of the total body deficit. Plasma potassium may even be raised initially due to disproportionate loss of water and catabolism of protein and glycogen.

Nonketotic Hyperosmolar State:

Clinical Features NKHS is most commonly seen in elderly individuals with type 2 DM. Its most prominent features include polyuria; orthostatic hypotension; and a variety of neurologic symptoms that include altered mental status, lethargy, obtundation, seizure, and possibly coma.

The prototypical patient is a mildly diabetic, elderly individual with a several week history of polyuria, weight loss, and diminished oral intake that culminates in mental confusion, lethargy, or coma. The physical examination reflects profound dehydration and hyperosmolality and reveals hypotension, tachycardia, and altered mental status.

NKHS is often precipitated by a serious, concurrent illness such as myocardial infarction or stroke. Sepsis, pneumonia, and other serious infections are frequent precipitants and should be sought thoroughly. Finally, the development of NKHS can be associated with the use of certain medications (thiazide diuretics, glucocorticoids, and phenytoin).

2. Chronic Complications of Diabetes Mellitus

a. Microvascular:

- Eye disease
- Retinopathy(nonproliferative/proliferative)
- Macular edema
- Cataracts
- Glaucoma
- Neuropathy
- Sensory and motor (mono- and polyneuropathy)
- Autonomic
- Nephropathy.

b. Macrovascular:

- Coronary artery disease
- Peripheral vascular disease
- Cerebrovascular disease

c. Other:

- Gastrointestinal (gastroparesis, diarrhoea)
- Genito urinary (uropathy/sexual dysfunction)
- Dermatologic

DIABETIC RETINOPATHY:

Diabetic retinopathy is the most common cause of blindness in adults between 30 and 65 years of age in developed countries.

Pathogenesis:

Hyperglycaemia increases retinal blood flow and metabolism and has direct effects on retinal endothelial cells and pericytes, loss of which impairs vascular autoregulation.the resulting in uncontrolled blood flow increases production of vasoactive substances and endothelial cell proliferation, resulting in capillary closure. This causes chronic retinal hypoxia and stimulated production of growth factors, including vascular endothelial growth factor (VEGF). VEGF acts via proteinkinase C to stimulate endothelial cell growth (causing new vessel formation) and increased vascular permeability (causing exudative damage).

Clinical Features Of Diabetic Retinopathy:

1. Microaneurysms
2. Retinal haemorrhages
3. Exudates
4. Cotton wool spots
5. Venous changes
6. Neovascularisation
7. Pre-retinal haemorrhage
8. Vitreous haemorrhage
9. Fibrosis

INTRARETINAL MICROVASCULAR ABNORMALITIES

Intraretinal microvascular abnormalities (IRMA) are dilated, tortuous capillaries which represent the remaining patent capillaries in an area where most have been occluded.

Neovascularisation:

This may arise from the venous circulation on the optic disc or the retina in response to areas of ischaemic retina. retinal detachment can occur due to contraction of adhesions between the vitreous and the retina.

Venous Changes:

These include venous dilatation (an early feature probably representing increased blood flow), 'beading' (sausage-like changes in calibre) and increased tortuosity including 'oxbow lakes' or loops.

Cataract:

Cataract is a permanent lens opacity and is the most common cause of visual deterioration in the elderly population.

The lens thickens and opacifies with age, and the increased metabolic insult to the lens in people with diabetes causes these changes to accelerate and occur prematurely. Very rarely, a type of cataract specific to diabetes occurs in young patients with poorly controlled

diabetes, called a ‘snow-flake’ cataract. This does not usually affect vision but tens to make fundal examination difficult.

Renal Complications Of Diabetes Mellitus:

The nephropathy that develops in type 2 DM differs from that of type 1 DM in the following respects:

a. Microalbuminuria or over nephropathy may be present when type 2 DM is diagnosed, reflecting its long asymptomatic period;
b. Hypertension more commonly accompanies microalbuminuria or nephropathy in type 2 DM
c. Micro albuminuria may be less predictive of progression to over nephropathy in type 2 DM. Finally, it should be noted that albuminuria in type 2 DM may be secondary to factors unrelated to DM, such as hypertension, congestive heart failure, prostate disease, or infection.

Other renal problems may also occur in individuals with DM. Type IV renal tubular acidosis (hyporeninemic hypoaldosteronism) occurs in many individuals with DM

NEUROPATHY AND DIABETES MELLITUS

Diabetic neuropathy occurs in approximately 50% of individuals with long-standing type 1 and type 2 DM. It may manifest as polyneuropathy, mononeuropathy, and/or autonomic neuropathy.

a.Polyneuropathy/Mononeuropathy:

The most common form of diabetic neuropathy is distal symmetric polyneuropathy. It most frequently presents with distal sensory loss. Hyperesthesia, parathesia, and pain also occur. Any combination of these symptoms may develop as neuropathy progresses. Physical examination reveals sensory loss, loss of ankle reflexes, and abnormal position sense.

b. Diabetic polyradiculopathy

c. Mononeuropathy (dysfunction of isolated cranial or peripheral nerves)

d. Autonomic Neuropathy

Cardiovascular Morbidity and Mortality:

Cardiovascular disease is increased in individuals with type 1 or type 2 DM. The Framingham Heart Study revealed a marked increase in several cardiovascular diseases in DM including peripheral vascular disease, congestive heart failure, coronary artery disease, myocardial infarction, and sudden death (risk increase from one- to fivefold).

The extremely high frequency of underlying cardiovascular disease in individuals with diabetes (especially in type 2 DM).The absence of chest pain ("silent ischemia") is common in individuals with diabetes.

Hypertension:

Hypertension can accelerate other complications of DM, particularly cardiovascular disease and nephropathy. Hypertension therapy should first emphasize life-style modifications such as weight loss, exercise, stress management, and sodium restriction.

YOGAM

Siddha science not only comprise the science of medicine but also every blessed theme on which the perpetual well-being of the whole human race is dependant. Yogam is one of the kayakalpam method that preserve physical and mental health. The term yogam means "union".Siddhars have defined yoga as an art which controls the mind by preventing it from getting distracted through sense organs and by uniting it with the divinity after realizing the truth of eternal bliss. Yogic physical culture would give vibrant health, real strength, the strength of the vital organs and muscular exercises, physical force and shape.

Only in this human birth one can get rid of sins and by virtue of good deeds get deeply absorbed in the pathways of yoga to attain the state of unity with entity. There is no system in the world to equal the yogam in giving health and simultaneously powers intellectual.

RELATIONSHIP BETWEEN YOGA AND AADHARANGAL (CHAKARAS):

The life energy pranan travels in the subtle body through a series of channels called nadis. These channels spins at a particular points which gets vortexes of energy that correspond to the chakras in the body. They are namely mooladharam,swasthitanam, manipooragam, anagatham, visuddhi, akkinai.These chakras are nothing but the storehouse of the finer aspects of solidified and mental modifications of the mind. They are control centres in the body and are related to different sections in the spine

Coccyx : *moolatharam*

Sacrum : *swadhitanam*

Lumbar : *manipooragam*

Dorsal : *anagatam*

Cervical : *visuddhi*

Akkinai : located between the eyebrows.

Each chakra regulates specific bodily systems in the body. For a balanced healthy life all the chakras must provide right amount of energy to the body. Our way of living in the world is highly dominated by the imbalanced functioning mainly of the lower three chakras.The pathway of the *prana vayu* gets affected in diseased condition of the body. This

in turn stagnates the the flow of pranan in the chakras. Practising yogasanam revitalizes and channelizes the flow of life energy.

Siddhar's science declares 64 kinds of yoga. Siva raja yogam and karpa yogam are one among them.

ஆச்சப்பா அறுபத்துநாலுயோகம் அடங்கலுமே பாடிவைத்தார் சித்தரெல்லாம்
ஏச்சப்பா உயிர்களையுங் கொல்லவென்று இன்பமுடன் அம்பிகா யோகமென்று
வாச்சப்பா நாவையுந்தான் மேலேயூன்றி வடிவான வாய்வுகளை கட்டும்போது
பேச்சப்பா கண் தெரிக்கும் வாய்வுதானும் பிரியமுடன் சயரோகமாந்தானே
நீதியனைஈரடி வுலாவிவந்தே நிலவும் ஆதனத்தில் மீண்டும் பொருந்தி
ஓதுசாதனையில் உறுதியோடிருப்பது யோகியர்க் கியல்பதாமன்றே

-சுப்பிரமணியர் ஞானம் 10

Siddhar agathiyar mentions about 9 asanams in his text Agathiyar paripooranam

சித்தமுடன் நேமவகை பத்துக்கண்டு
தெளித்துசிவ யோகமது திறமாய்நிற்க
வெந்தியுள்ள ஆசனந்தா னொன்பதப்பா
விபரமுள்ள சொல்லுகிறோன் விரும்பிக்கேளு
பத்தியுள்ள கொத்திகங்கோ முகமும்பத்மம்
பதிவான பீரம்பத்திரஞ் சிங்கமொடுமுத்த
முத்தியுள்ள மயூரமொடு சுகமதுவுமைந்தா
முதலான நவக்கிரகம் ஒன்பது ஆசனமே
ஆசனமாய் நின்றதொரு ஒன்பதையுங்கண்டு
அதிலிருந்து தவசுசிவ யோகாஞ்செய்தால்
பூசணமாய் நின்றிலங்கு மாசனந்தான்மைந்தா
புத்தியுட னாசனமே லிருந்துகொண்டு
வாசனையாய் மனதுகந்து வாசிபார்த்து
மனமகிழ்ந்து சிவயோக நிலையில்நின்று
நேசமுடன் பிராணாயஞ் செய்துகொண்டு
நிச்சயமாய்க் கற்பூர தீபம்பாரே.

-அகத்தியர் பரிபூரணம் 1200

Siddhar thirumoolar the renowned sage who authored Thirumanthiramhas assured that all human disease can be cured through yogasanam and pranayamam. Yogam focuses on ashtanga yogam namely Iyamam , Niyamam, Pranayamam, Asanam, Prathiagaram, Tharanai, Dhiyanam, Samathi.

காணவே அட்டாங்க மெட்டுங்கேளு
கருவாகச் சொல்லுகிறேன் கண்டுகொண்டு
பூணவே இமயமொடு நேமமைந்தா
புத்தியுட னாசனமும் பிராணாயந்தான்
தோணவே தாராணையும் பிரத்தியாகாரம்
சூட்சமென்ற சமாதியொடு தியானம்பத்தும்
பேணவே யெட்டுமடா அட்டாங்கயோகம்
பெருமையுள்ள காவியத்தைக் கண்டுதேறே.

-அகத்தியர் பரிபூரணம் 1200

Iyamam means good thoughts, niyamam means good deeds, asanam means posture, pranayamam means regulating breath, prathiyagaram controlling the mind, tharanai means concentration, dhyanam means thinking about one aspect, Samadhi attained of heavenly stage.

Thirumoolar have mentioned that there are numerous asanam but stresses only eight among them soththirasanam, gomukhasanam, padmasanam, veerasanam, simhasanam, bhadrasanam, mukthasanam and sukhasanam.

பத்திரம் கோமுகம் பங்கயம் ஆசனம்
சொத்திரம் வீரம் சுகாதனம் ஓரேழும்
உத்தமாம்முது ஆசனம் எட்டெட்டுப்
பத்தொடு நூறு பல ஆசனமே.

-திருமந்திரம்

According to thirumoolar, regular practise of yogasanas can monitor the excess or shortage of pitham, vatham and kabam. He also states that when yoga is practised early in the morning pitham is reduced, causing the body to be more relaxed. When yoga is practised around mid-day vatham is controlled and in the evening kabam is controlled.

ஆதனத்திருந்தே சாதனைபுரிந்தால் அடங்கிடாப் பொறிபுலனடங்கும்
ஆதனத்திருந்தே சாதனைபுரிந்தால் அடங்கிடு மனோவிஷயங்கள்
ஆதனத்திருந்தே சாதனைபுரிந்தால் அறிவு அறியாமைக ளொழியும்
சாதனைபுரிந்தால் அகண்டவீ டடைவதுநிசமே

-சுப்பிரமணியர் ஞானம் 1200

Asanas are helpful in the practice of yoga in the following ways,

1. An uncommon power of fortitude and control of the different muscles of the body are acquired.
2. The entire physical system id brought under the control of will in a vivid manner.
3. The body is kept free from all impurities with the nervous system kept unclogged for the free exercise of breathing.
4. Disease are cured and the way of the attainment of health and perpetual life is made clear.
5. The five senses can be controlled, rising thoughts averted mind concentrated
6. Some of the primary differences between pure exercise and yoga are

Exercise	**Yogasanam**
Is practiced after muscle are stronger	May be practiced at any age
Takes a long time for results	Produces faster results
Requires greater food intake	Needs less food intake
Requires equipment	Needs no equipment
Builds muscle	Activates glands
Tires mind / body	Rejuvenates mind / body
Causes shortness of breath	Elongates breathing
Creates aggression	Creates passivity

Yogasanam techniques and benefits:

Each Yogasanam is indicated for a definite effect in a particular region of the system by stimulating the internal organs to function in a normal way and to coordinate bodily functions. Rejuvenation / regeneration of cells of pancreas due to abdominal stretching during yogam , which may increase utilization and metabolism of glucose in peripheral tissues, liver, and adipose tissues through enzymatic process. More active practices followed by relaxing ones lead to deeper relaxation than relaxing practices alone, Muscular relaxation, development and improved blood supply to muscles might enhance insulin receptor expression on muscles causing increased glucose uptake by muscles and thus reducing blood sugar. Yogam postures can lead to improvement in the sensitivity of the beta Cells of the pancreas to the glucose signal and also the improvement in insulin sensitivity in turn can be due to the cumulative effect of performing the postures. yogam may also lower oxidative stress and blood pressure; enhance pulmonary and autonomic function, mood, sleep, and quality of life; and reduce medication use in adults with Diabetes Mellitus.

Suryavanakkam:

STEP 1:

Stand straight, facing forward with normal breathing, keep the feet together, the toes, and heels in the straight line, big toes and centre of the inner ankle touching each other. Keep the weight evently on the heels.

Keeping the leg facing forward, join both the palms together.Place the hand near the chest with the thumb touching the middle of the chest Spread the elbow outward from the body and take a deep inhalation and slow exhalation.

STEP 2

Keeping the knees straight and heel down, bring the thighs and hip forward and start arching your body backwards.Inhale while increasing the arch slowly by raising the arms and stretched back over the head.When your hands are on both sides of your head, allow your upper arms to touch your ears.

STEP 3

Keeping the knee straight and heels down, bend the body forward.Exhale while you bend your body forward and down.Keep your hands flat on the floor at the sides of the legs.

STEP 4

Extend your left leg back while inhaling and drop the knee to the floor.Bend your right knee between the hands, the right thigh touches the right side of the chestPalms and the right foot must be in the same lineConcentrate at the centre of the eyebrow by pushing your head backward.

STEP 5

Press the palms on the floor, and simultaneously raise the back and lower the head between the arms.The heels should always be flat on the floor maintain this posture.

STEP6

Exhaling bring the right leg back to join with the left leg with chin touching the ground.

STEP 7

Raise the chest upwards with help of your hands and arch the spine along your head backward.Stretch your foot backwards, keeping your knees straight.Repeat steps 5 to 1.

Benefits:

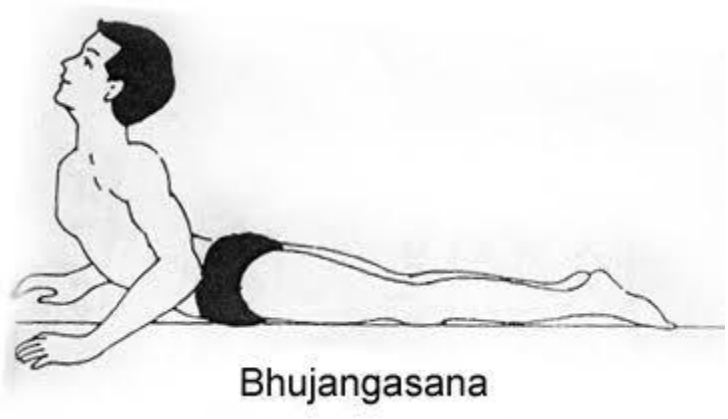
- It increases blood circulation to all parts of the body. It decreases degenerative changes in the joints. Improves the nervous stimulation
- Improves digestion
- Improves eyesight
- It increases immunity
- It control diabetes.

Bhujangasanam

- Lie on your chest with the palms down and fingertips in line with the shoulder.
- Applying minimum pressure on your hands, rise your head high and bend back like a snake breathe normally.
- Then lower your head slowly.
- Hold for 15 seconds.

Benefits:

- The stomach muscles are pulled and blood flows freely to the front of the body.
- The backbone gets stronger.
- The chest expands and the ribs get strengthen.

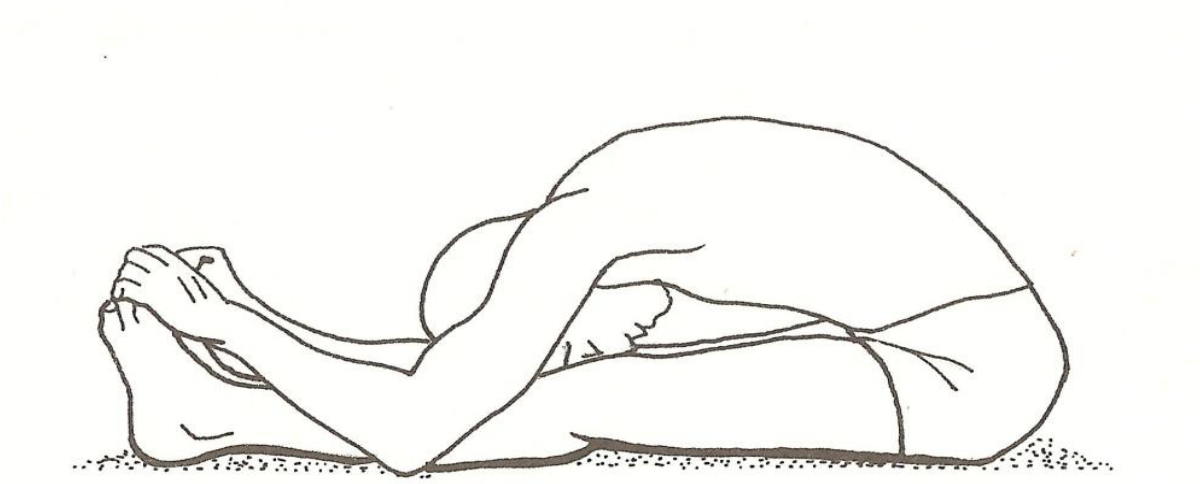


Patchimothasanam:

- Sit up straight and keep both legs together.
- Stretch your arms up close to the side of the head near the ears.
- Inhale and bend forward to hold your feet with your hands.
- Then try to touch your knees with your face.
- Stay in this position for 10 seconds.

Benefits

- Stomach muscles will get stronger.
- Liver spleen stomach pancreas will be reactivated .when performed correctly any disease of the organs will recede.
- Appetite will become normal.
- Cures diabetes.

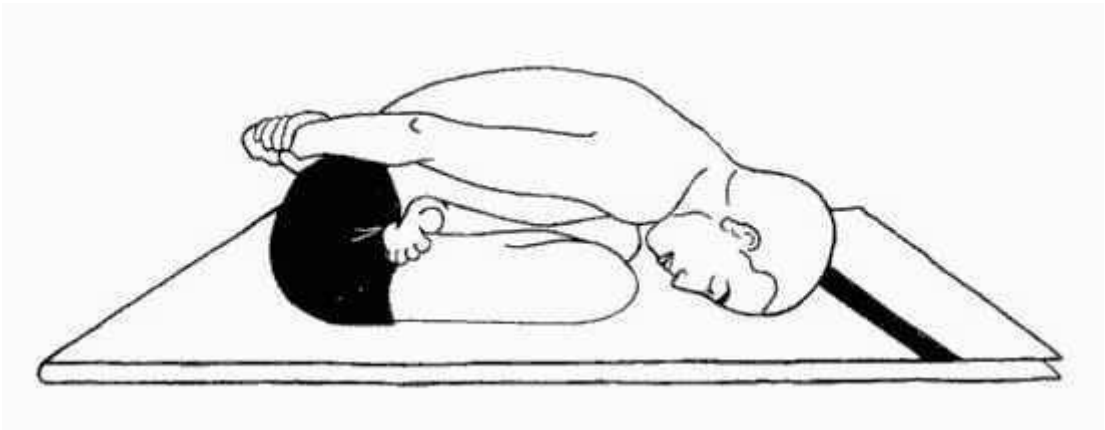


Yoga mudra:

- Sitting in *Padmasanam,* fold your palms together comfortably behind your backs, or touch elbows with opposite hands.
- Your chin should touch chest.
- In this position exhale and bend forward so that your forehead touches the ground.
- After being in position for few seconds, inhale and rise our head and sit erect.

Benefits:

- The muscles in the back bones and stomach organs feel refreshed.
- The liver and spleen will feel the pleasure and begin to work well.
- Cures diabetes.
- The waist line reduces and spine is straightened.
- Cures indigestion and constipation.



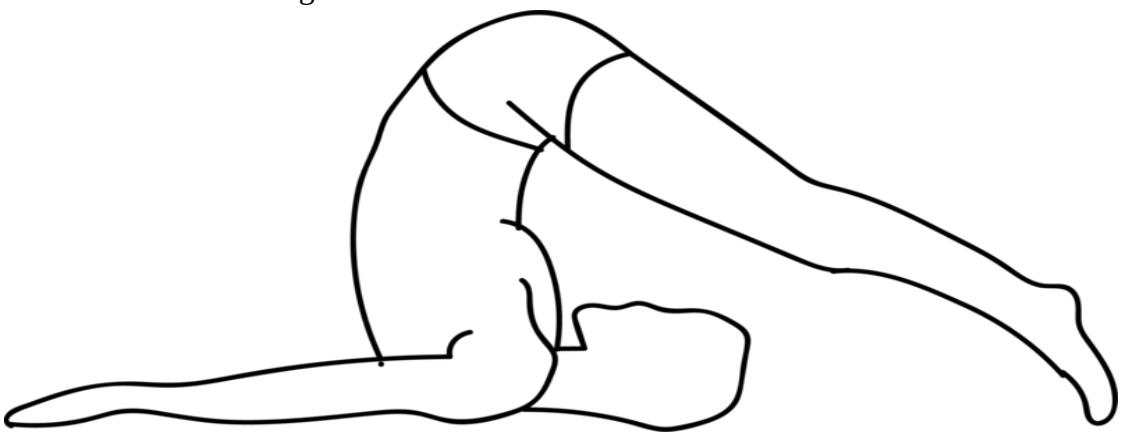
Halasanam:

Procedure:

- Lie on your back, keep the leg in contact and stretch your hands on the sides of the body.
- Keeps the palm touching the floor. Inhale a little, raise the legs above the waist and bend them above the body backwards. Touch the floor with the toes have touched the floor, bend the back well and press the chin with the chest.
- The back of the head (occipital region) and neck should touch the floor.
- Extend the legs to the back of the head as for as they would go.
- Stimulates **visuddhi chakram**.

Benefits:

- Stretches all muscles and ligaments in the practitioner's calves and thighs, resulting in greater flexibility.
- Therapeutic for leg cramps.
- It stimulates thyroid, parathyroid, throat and abdominal organs.
- Therapeutic for menopause, infertility, insomnia, headache, sinusitis.
- Promotes good digestion.
- Helps to relieve gas and upper/lower back pain or discomfort.
- Relieves stress and fatigue.



Bavanamuktasanam:

- **Method**
- Lieflatonyourbackandkeepthelegsstraightandbreathedeeply.
- Inhaleslowlyandliftthelegsandbendintheknee.Bringupwardstothe chesttillyourthightouchestostomach
- Hugyourknees inplaceand lock yourfingers.
- Trytotouchthekneewithyournosetip.Holdthispositionforfewseconds
- Nowexhaleslowly andcomebackto theinitialposition

Benefits

- It cures acidity, indigestion, constipation.
- Helpfulforarthritispainandheartproblems.
- Strengthensbackmuscleandcuresbackpain.
- Itgivesflatstomach.
- Verybeneficialforreproductive organandformenstruationdisorder.
- Specifically stimulates**Manipurakam chakram**.

Vakrasanam:

Method:

- Sit down stretching your legs forward on the ground.
- Keep your hands beside your thighs or buttocks.
- Bend your right leg straight and stretched.
- Keep the left foot beside the right knee and the left knee raised upward.
- Inhale and raise the arms shoulder high, keeping the elbows straight.
- Exhaling, twist to the left, place the right arm by the outer side of the left knee and hold the left ankle with the right hand.
- Take the left hand behind the back keeping the palms on the floor.
- Look backward towards the left side.
- Hold on the position. Practise both sides.

Benefits:

- Increases the elasticity of the spine and tones the spinal nerves.
- Stretches the muscles.
- Helps to get relief in stiffness of vertebrae.
- Massages the abdominal organs.

- Reduces belly fat.
- Regulates the secretion of digestive juices useful for different digestive disorders.
- Loosens the hip joints, relieving stiffness.
- Flab on the lateral side of the abdomen gets reduced.
- Specifically stimulatesManipurakam chakram.

Padmasanam:

- Cross your legs over the left and right thighs.
- Both the knee joint should touch the floor.
- Both heels should touch the abdomen.
- Both hands should be in *chin mudra*.

Benefits:

- Improves the blood flow to the abdomen.
- Improves appetite.
- This is a good posture to perform *pranayamam*

Naadisuthi pranayamam

Sit in a comfortable posture (Padmasanam, sugasanam, vajrasanam)

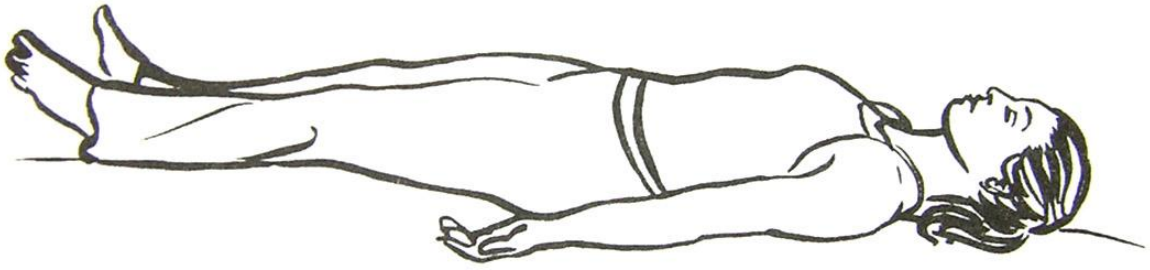
- Lefthandinchinmuthraiwithclosedeyes.
- Closetheright nostrillusingrightthumb.
- Inhale slowly and deeply through the left nostrils, followed by holding the air for few seconds by closing the right nostrils by thumb and left nostrils by ring and little finger of right hand.Exhale through right nostrils
- Inhale by right nostrils holding the air by closing both nostrils exhale through left nostrils.Repeat the same for few minutes

Savasanam (shanthi aasanam):

Method:

- Lie down on the floor with an even surface.
- Palm facing upward and half a foot gap in between the heels, keep the legs in relax manner.

Benefits: Relieves physical and mental tiredness.



SYZYGIUM CUMINI

Botanical Name : *Syzygium cumini*

Family : Myrtaceae

Part used : Bark

Organoleptic Characters

Taste : *Thuvarppu*

Potency : *Thatpam*

Pirivu : *Kaarppu*

Chemical Constituents:

Anthocyanins, glucoside, ellagic acid, isoquercetin, kaemferol and myrecetin. The seeds are claimed to contain alkaloid, jambosine, and glycoside antimellin

General properties:

ஆசியநோய் காசம் அசிர்க்கரஞ்சு வாசவினை
கேசமுறு பால கிரகநோய்-பேசரிய
மாவியங்க லாஞ்சனமிவ் வன்பிணியெ லாமேகும்
நாவலுறு பட்டையத னால்.

Medicinal uses:

The bark is astringent, sweet, sour, acrid, refringerant, carminative, diuretic, digestive anthelmintic febrifuge

ACACIA NILOTICA

Botanical Name : *Acacia nilotica*

Family : Mimosaceae

Part used : Bark

Organoleptic Characters

Taste **:** *Thuvarp*pu

Potency **:** *Thatpam*

Pirivu :*Inippu*

ChemicalConstituents:

Bark yields several polyphenol compounds,,catechol, epicatechin, epigallocatechin, quercetin,gallic acid, leucocyanidingallate, sucrose, tannin, m-digallic and chlorgenic acid

Medicinal uses:

Bark decoction is used to gargle in sore throat and tooth ache; dry powder applied externally in ulcers.

SALACIA RETICULATA

Botanical Name : *Salacia reticulata*

Family : Hippocrateaceae

Part used : Root

Organoleptic Characters

Taste :*Thuvarppu*
Potency :*Thatpam*
Pirivu :*Kaarppu*

Chemical Constituents:

Triterpenes, hydrocarbons and sitosterol,mangiferin, kotalanol, and salacinol

General properties:

தீதில் உடலழிஞ்சில் செய்யுங் குணங்கேளாய்!
ஒதுமது மேக மொழிப்பதல்லால்-வாதத்தில்
வந்தசலம் பித்தசல மாகபச்ச லந்தாகத்
தொந்தசல மும்போக்குஞ் சொல்

Medicnal uses:

The roots are acrid, bitter,thermogenic,urinary astringent,anodyne, anti-inflammatory, depurative, liver tonic and stomachic

TERMINALIA ARJUNA

Botanical Name: *Terminalia arjuna*

Family : Combretaceae

Part used : Bark

Organoleptic Characters

Taste : *Thuvarppu*

Potency :*Thatpam*

Pirivu :*Karppu*

Chemical Constituents:

Arjunolicacid,tomentosic acid,b-sitosterol,ellagic acid, saponin, leucodelphidin,arjunine.arjunetin,tannin, pyrocatechol.

General properties:

ஒதமெனு நீரிழிவை யோட்டும் பிரமேகங்
காதமென வோடக் கடத்துங்காண்-போத
மயக்க மொடுதாக மாறாச் சுரத்தின்
தயக்கமறுக் கும் மருதஞ் சாற்று

Medicinal uses:

The barks are acrid, astringent, sweet, cooloing, demulcent, cardiotonic, styptic, antidysentic, lithotryptic and expectorant

TERMINALIA BELLERICA

Botanical Name: *Terminalia bellerica*

Family : Combretaceae

Part used : Seeds

Organoleptic Characters:

Taste : *Thuvarppu*

Potency : *Veppam*

Pirivu : *Inippu*

General properties:

ஆணிப்பொன் மேனிக் கழகும் ஒளியுமிகும்
கோணிக்கொள் வாதபித்தக்கொள்கைபோம்-தானிக்காய்
கொண்டவர்க்கு மேகமறும் கூறா அனயற்றணியும்
கண்டவர்க்கு வாதம்போம் காண்.

Chemical Constituents:

Fruit contains about 17%tannin and β-sitosterol, gallic acid, ellagic acid, ethyl gallate, galloyl glucose and chebulagic acid.

Medicinal uses:

The fruits are astringent, acrid, sweet, thermogenic, anodyne, styptic, narcotic, digestive, anthelmintic, aperient, ophthalmic, antipyretic and rejuvenating.

TERMINALIA CHEBULA

Botanical Name : Terminalia chebula
Family : Combretaceae
Part used : Seeds

Organoleptic Characters

Taste : *Thuvarppu*
Potency : *Veppam*
Pirivu :*Inippu*

Chemical Constituents:

Fruits contain 30% astringent substance; astringency due to the characteristic principle chebulinic acid also contain 20-40 % gallic acid, resin etc. And a purgative glycoside of athroquinone derivative.

General properties:

தூடை கழத்தக்கி தாலு குறியிவிடப்
பீடை சிலிபதமுற் பேதிமுடம் -ஆடையெட்டாத்
தூலமிடி புண்வாத சோணிகா மாலையிரண்
டாலமிடி போம்வரிக்கா யால்

Medicinal uses:

Chebulinic acid exhibits antispasmodic action on smooth muscle similar to papaverine. The fruits are astringent,sweet, acrid,bitter, sour, thermogenic,antiseptic,and stomachic.

PHYLLANTHUS EMBLICA

Botanical Name :*Phyllanthus emblica*

Family : Euphorbiaceae

Part used : Seeds

Organoleptic Characters

Taste :*Thuvarppu,Pulippu,Inippu*

Potency :*Thatpam*

Pirivu : *Inippu*

Chemical Constituents:

The major amino acids are alanine, aspartic acid, glutamic acid, lysine, and proline.

General properties:

ஆகவன லஞ்சசிஅ சிர்க்கென்பு ருக்கிகண்ணோய்
தூக முதிரவித்தந் தாது நஷ்டம்-மேகனத்தின்
இல்லிமுள்ளி போலருகல் எண்கா மியவியறங்கம்
நெல்லிமுள்ளி யாற்போ நினை.

Medicinal uses:

The fruits are sour, astringent, bitter, acrid, cooling, carminative, ophthalmic, stomachic, laxative, diuretic antipyretic.

STRYNCHNOS POTATORUM

Botanical Name : *Strynchnos potatorum*

Family :Logainaceae

Part used :Seeds

Organoleptic Characters

Taste : *Kaippu*

Potency : *Veppam*

Pirivu :*Kaarppu*

Chemical Constituents:

Loganin, mannose, sucrose, arachidonic, lignoceric, linoleic, oleic, palmitic, and stearic acids, β-sitosterol, stigmasterol,

General properties:

தேற்றாம் விதையதுதான் தீபனத்தைப் போக்குமனல்
ஆற்றுமிரு கண்ணுக் கருமருந்தாம்-கூற்ற
யிருத்துங் கிரிச்சலத்தை எங்குமிலா தோட்டுங்
குருத்துவ முண் டாக்குங் குறி.

Medicinal uses:

The seeds are sweet, bitter, astringent, demulcent, emetic, diuretic, refrigerant, appetiser, tonic and water purifier.

ARECHA CATECHU

Botanical Name : *Arecha catechu*

Family : Palmaceae

Part used : Seeds

Organoleptic Characters

Taste : *Thuvarppu*

Potency : *Veppam*

Pirivu : *Kaarppu*

Chemical Constituents:

The seeds contain tannin, catechin (70%in the young fruit 15-20%in over-ripe fruits), lipids consisting of laurin, olein, myrstin; glucides 50-60%alkaloids, arecoline, arecaidine, guvacine and guvacoline.

Medicinal uses:

The pericarp is effective in the treatment of flatulence, oedema, dysuria, and hyperemesis of pregnancy. The kernel is used to treat diarrhoea ad dysentery. Arecoline induces papillary contraction and decreases ocular tension in glaucoma.

FICUS RACEMOSA

Botanical Name :*Ficus racemosa*

Family : Moraceae

Part used : Bark

Organoleptic Characters

Taste : *Thuvarppu*

Potency : *Thatppam*

Pirivu : *Inippu*

Chemical Constituents:

Glycosides, β-sitosterol,lupeol, tannins,psoralenes

General properties:

வீறு கடுப்பிரத்தம் வெண்சீத ரத்தமொடு
நாறுவிர ணங்களெலாம் நாடாவாம் -கூறுங்கால்
அத்திதரு மேகம்போம் ஆயிழையே! எஞ்ஞான்றும்
அத்திப்பாற் பட்டைக் கறி.

Medicinal uses:

The extract of the fruit is used in diabetes, leucoderma and menorrhagia.It is used locally to relieve inflammation of skin wounds, lymphadenitis, sprains, fibrousitis.

CASSIA AURICILATA

Botanical Name : *Cassia auriculata*

Family : Fabacae

Part used : Bark

Organoleptic Characters

Taste :*Thuvarppu*

Potency :*Thatppam*

Pirivu :*Inippu*

Chemical constituents:

Alkaloids, tannins flavonoids, glycosides, saponins

General properties:

சொல்லுதற்கு மட்டோ தொலையாத மேகநீர்
எல்லா மொழிக்கு மெரிவகற்று-மெல்லவச
மாவாரைப் பம்பரம்போ லாட்டுந் தொழிலணங்கே!
யாவாரை மூலி யது.

Medicinal uses:

The stem bark is used in treatment of diabetes, diarrhoea, liver disease, urinary tract disease,constipation and joint pain.

Pharmacological activities of ingredients of Maruthampattai kudineer

TERMINALIA CHEBULA

Naik G H et al; observed that aqueous extract of T. chebula was an excellent scavenger of DPPH radicals and inhibited xanthine/xanthine oxidase activity. Kannan et al;explained that*T. chebula* fruit and seeds exhibited dose dependent reduction in blood glucose of streptozotocin induced diabetic rats in toxicity studies and also had renoprotective activity. Gandhipuram Periasamy Senthilkumar et al; described that the ethanolic dry fruit extract showed reduced blood glucose, glycosylated hemoglobin, urea, and creatinine as well as fructose, Hexose, hexosamine and sialic acid in the diabetic rats.The efficacy of the fruit extract was comparable with glibenclamide, a known hypoglycaemic drug

TERMIALIA ARJUNA

Warrier PK, Nambiar VPet al; has described that the bark has astringent, demulcent, expectorant, cardiotonic, styptic, antidysenteric, urinary astringent activity, and has shown to be useful in fracture, ulcers, leukorrhea, diabetes, anemia, cardiopathy, and cirrhosis.**B.Ragavan** et al;illustrates that thepresence of tannin, saponin, flavonoids and other constituents of T.arjuna bark extract exhibited antidiabetic activity by enhancing the peripheral utilization of glucose by correcting the impaired liver and kidney glycolysis and by limiting its gluconeogenic formation similar to insulin. **Amit Gupta et** al;suggests that aqueous stem bark extract of Terminalia arjuna and Emblica officinalis showed anti-diabetic activity with respect to enhancement of granulocytes count and decrease in free haemoglobin content including total cellular content in diabetic human.

SYZGIUM CUMINI

Sengupta P et al; portrays that the stem bark is rich in betulinic acid, friedelin, epi-friedelanol, β-sitosterol, eugenin and fatty acid ester of epi-friedelanol**Tripathi and Kohli** et al; studied the antidiabetic activity of bark extract of *Syzygium cumini* on streptozotocin (STZ)-induced diabetic Wistar albino rats and reported that 30 minutes prior administration of *Syzygium cumini* (L.) extracts before oral glucose loading significantly decreased the rise in postprandial blood glucose levels .However the result was less significant than glibenclamide.

ARECHA CATECHU

Chempakam B et al;has reported that arecoline a major constituent of Areca catechu have hypoglycemic activity in an animal model of diabetes upon subcutaneous administration. The Subcutaneous administration of alkaloid fraction of Areca catechu (0.05_/0.5 mg/kg) in alloxanized rabbits (140 mg/kg) showed significant hypoglycemic effect lasting for 4/6 hours. Inokuchi J, Okabe H et al describes that Areca tannin inhibits the pressure response angiotensin I and II thus showing a regulatory effect on blood pressure.

FICUS RACEMOSA

Kar A, Choudhary et al; reports that β-sitosterol isolated from the stem bark was found to possess potent hypoglycemic activity when compared to other isolated compounds.Jahan IA, Nahar et al explains that ethanol extract of fruits, exhibited significant antioxidant activity in DPPH free radical scavenging assay. 3-O-(E)-Caffeoyl

quinate showed significant antioxidant activity. Chopra RN et al ; postulatesthatan infusion of bark which is astringent in nature is employed as mouth wash in spongy gum condition, dysentery, menorrhea, hemoptysis, and diabetes.

SALACIA RETICULATA

Matsuda et al; reported the active fraction from S. reticulate shows alpha-glucosidase inhibitory effect which is the primary activity responsible for its hypoglycaemic effect Shimoda et al. demonstrated that an aqueous extract of SR dose dependently suppressed the serum glucose level induced by sucrose, maltose and alpha starch but not that induced by glucose and lactose.Yoshikawa et al ;explains that the two potent alpha glucosidase inhibitors, salacinaol and kotalanol have been identified consistently in studies and are believed to be responsible for the attenuation of postprandial glucose in rat models as well as humans.

STRYCHNOS POTATORUM

Dhasarathan P, et al., evaluated the anti-diabetic activity in the ethanol extract of the plant on blood sugar level, which proved to be effective even at a lower dose (100 mg/kg) in decreasing blood sugar level in alloxan treated rats. The plant extract almost brought down blood glucose level by 50% in diabetic animals.Ekambaram et al;demonstared that SPP and SPE of *Strychnos potatorum* seeds possess hepatoprotective and antioxidant activities against CCl_4-induced acute hepatic injury.

ACACIA NILOTICA:

Infusion of bark (1½ ounces to one pint of water) is given in chronic diarrhoea and diabetes mellitus in doses of 1½ to 2 ounces twice a day The extracts of Acacia nilotica pod exhibited strong and effective antioxidant property in vitro and in vivo by chelation to metal ions as well as scavenging free radical. It also prevents strand break formation in supercoiled plasmid DNA and protein oxidation

TERMINALIA BELLERICA:

Ramesh Kumar et al demonstrated that in vitro assessment of the antioxidant activity of ethanolic fractions of Terminalia bellerica to scavenge 2, 2- Diphenyl-1-picrylhydrazyl (DPPH) and highly reactive hydroxyl radicals showed that the semi pure compounds present in the fractions are useful potential source of antioxidants ¨ M.C.Babu et al; demonstrated that administration of T. belerica extract did not have any significant effect on serum

glucose level in alloxan diabetic rats during first five days but started reducing from 6th day onwards On 9th daywhen compared with that of control diabetic animals serum glucose in extract treated animals was found to be reduced to 54% .

PHYLLANTHUS EMBLICA:

Priya et al; postulates that the methanolic seed extract of Emblica officinalis has promising free radical scavenging activity of 1,1, Diphenyl-2-picryl-hydrazil (DPPH) in a concentration dependant manner.Jayweera et al; has documented that *Emblica officinalis* is proved as an important inhibitor of Aldose reductase which has its involvement in the development of secondary complications of diabetes including cataract.

CASSIA AURICULATA

Daisy et al; investigated the effect of Cassia auriculata crude extracts on plasma glucose level in normal and experimental rats. STZ-treated diabetic rats showed significant increase in the levels of blood glucose when compared to normal rats.a significant elevation in the levels of fasting blood glucose, glycosylated haemoglobin (HbA1c), serum insulin, C-peptide and liver enzyme were observed.Kolar et al; evaluated the antioxidant activity of aqueous and ethanol extracts of four plants from the genus Cassia by various antioxidant assays, including ferric reducing antioxidant power (FRAP), DPPH free radical scavenging, metal chelating activity, phosphor molybdenum reducing power, hydrogen peroxide radical scavenging, hydroxyl radical scavenging, deoxyribose degradation and β-carotene bleaching assay. All the extracts showed antioxidant activity in the tested methods. Among the four species, Cassia auriculata has been found to possess highest activity in most of the tested models

MATERIALS AND METHOD

Source of raw drugs:

The required raw drugs for the preparation of ***Maruthampattai kudineer*** were procured from the raw drug shop, Parrys, Chennai.

Raw drugs Identification and authentication:

These ingredients were identified and were authenticated by Dr.D.Aravind M.Sc, Asst Prof, Medicinal Botanist at NIS, Tambaram sanatorium, Chennai.

Ingredients:

1. Maruthampattai (*Terminalia arjuna)* -350 gms
2. Navalpattai *(Syzygium cumini)* - 350 gms
3. Karuvellampattai *(Acacia nilotica)* - 350 gms
4. Athipattai *(Ficus racemosa)* - 350 gms
5. Avaraithol *(Cassia auriculata)* - 350 gms
6. Kadalalinjilpattai *(Salacia reticulata)* - 700 gms
7. Thetrankottai *(Strychnos potatorum)* - 35 gms
8. Kalipakku *(Areca catechu)* -35 gms
9. Kadukkai thol *(Terminalia chebula)* -35 gms
10. Nellivatral *(Phyllanthus emblica)* - 35 gms
11. Thandrikai thol *(Terminalia bellirica)* - 35 gms

RAW DRUGS OF MARUTHAMPATTAI KUDINEER

THANDRIKKAI

KARUVELLAM PATTAI

NELLIMULLI

KADALAZHINJILPATTAI

MARUTHAMPATTAI

KADUKKAI

KALIPPAKKU

ATHIPPATAI

THETRAN

AVARAIPAATAI

NAVAL PATTAI

MARUTHAMPATTAI KUDINEER

METHOD OF PURIFICATION & PREPARTION:

Purification methods:

- Barks General Methods:

  Each bark was cleaned with a clean cotton cloth and dried after removing the peel. Ref. *Sigicha Rathana deepam*

- Thaetran vithai(seed) :

  Seeds were soaked in the cow‘s milk, then washed and dried.

  Ref .*Agathiyar gunavagadam*

- Kalipakku:

  It is boiled and dried.

  Ref .*Agathiyar gunavagadam*

- Thandrikkai thol,kadukkai&Nelli mulli:

  The seeds were removed and the remaining part was used.

  Ref .*Agathiyar gunavagadam*

Preparation:

மருது டனுவாரை தாவல் வருமத்திக் கருவேற் பட்டை
தருமது பலங்கள் பத்து தன்னுடன் கலந்து கூட்டி
வருமது கடலிராஞ்சி வருபல மிருபதாக
பருவிரைதேற்றுக் களிப்பாக்கு திரிபலைபதக்கு
நீருழக்காய்க் கொள்ளே.
- அகத்தியர் 2000

The above ingredients were ground into coarse powder. 5gm of *Marutham pattai kudineer powder*was taken and 240 ml of water was added, boiled and reduced to1/4th of the part, i.e 60 ml.

Dosage **:** 60 ml.bid

Duration **:** 90 days

Reference **:** AGATHIYAR 2000 part III (pg.no:3)

BIOCHEMICAL ANALYSIS

Biochemical Analysis of Maruthampattai kudineer was done at the Biochemistry lab atNational Institute of Siddha, Chennai by the method of Kolkate.

Preparation of Extract:

5ml of sample was taken in a 250ml clean beaker and added with 50ml of distilledwater. Then it is boiled well for about 10 minutes. Then it was cooled and filtered in a 100mlvolumetric flask and made up to 100ml with distilled water. This preparation was used forthe qualitative analysis of acidic/basic radicals and biochemical constituents in it.

Procedure:

Test for Acid Radicals

Test for Sulphate:

2ml of the above prepared extract was taken in a test tube to this added 2ml of 4% dilammonium oxalate solution. A cloudy or white precipitate is observed

Test for chloride:

2ml of the above prepared extracts was added with 2ml of dil.HCl is added until the effervescence ceases off. Cloudy appearance indicates the presence of chloride.

Test for Phosphate:

2ml of the extract was treated with 2ml of dil.ammonium molybdate solution and 2ml ofcon.HNo3.Cloudy yellow appearance indicates the presence of phosphate.

Test for carbonate:

2ml of the extract was treated with 2ml of dil. magnesium sulphate solution.Cloudy appearance indicates the presence of carbonate.

Test for Nitrate:

1gm of the extract was heated with copper turning and concentrated H_2 So_4 and viewed thetest tube vertically down. Evolution of brown gas indicates the presence of nitrate.

Test for Basic radicals

Test for lead:

2ml of the extract was added with 2ml of dil.potassium iodine solution. Yellow precipitate indicates the presence of lead.

Test for copper:

One pinch (25mg) of extract was made into paste with con. HClin a watch glass andintroduced into the non-luminous part of the flame. Blue colour flame indicates the presence of copper.

Test for Aluminium:

To the 2ml of extract dil.sodium hydroxide was added in 5 drops to excess. No characteristic changes indicates its presence

Test for Iron:

a. To the 2ml of extract add 2ml of ammonium thiocyanate solution. Appearance of blood red colour indicates the presence of iron

b. To the 2ml of extract 2ml of ammonium thiocyanate solution and 2ml of con HNo_3 is added.Appearance of blood red colour indicates the presence of iron

Test for Zinc:

To 2ml of the extract dil.sodium hydroxide solution was added in 5 drops to excess anddil.ammoniumchloride was added. Presence of white precipitate indicates the presence of zinc

Test for Calcium

To 2ml of the extract was added with 2ml of 4% dil.ammonium oxalate solution. Cloudy appearance and white appearance indicates the presence of calcium

Test for Magnesium:

To 2ml of extract dil.sodium hydroxide solution was added in drops to excess**.** White precipitate indicates the presence of magnesium.

Test for Ammonium:

To 2ml of extract 1 ml of Nessler's reagent and excess of dil.sodium hydroxide solution were added. Brown colour indicates the presence of ammonium.

Test for Potassium:

A pinch (25mg) of extract was treated with 2ml of dil.sodium nitrite solution andthen treated with 2ml of dil.cobalt nitrate in 30% dil.glacial acetic acid.Yellowish precipitate indicates the presence of magnesium.

Test for Sodium:

2 pinches (50mg) of the extract is made into paste by using HCl and introduced intothe blue flame of Bunsen burner.Yellowish flame indicates the presence of sodium.

Test for Mercury:

2ml of the extract was treated with 2ml of dil.sodium hydroxide solution.Yellowish precipitate indicates the presence of mercury.

Test for Arsenic:

2ml of the extract was treated with 2ml of dil.sodium hydroxide solution. Brownish red precipitate indicates the presence of magnesium.

Test for phytochemicals:

Test for Starch:

2ml of extract was treated with weak dil.Iodine solution. Appearance of blue colour confirms its presence.

Test For Reducing Sugar:

5ml of Benedict's qualitative solution was taken in a test tube and allowed to boil for 2minutes and added 8 to 10 drops of the extract and again boil it for 2 minutes. The colour changes are noted.

Test for the Alkaloids:

a) 2ml of the extract was treated with 2ml of dil.potassium Iodide solution.The colour changes are noted.

b) 2ml of the extract was treated with 2ml of dil.picric acid.The colour changes are noted.

c) 2ml of the extract was treated with 2ml of dil.phosphotungstic acid.The colour changes are noted.

Test for Tannic Acid:

2ml of extract was treated with 2ml of dil.ferric chloride solution.black precipitate indicates the presence of tannic acid.

Test for Unsaturated Compound:

To the 2ml of extract 2ml of dil.Potassium permanganate solution was added.the Potassium permanganate solution is not decolourised in the presence of unsaturated compound.

Test for AminoAcid:

2 drops of the extract was placed on a filter paper and dried well. 20ml of Burettereagent is added. Violet colour indicates the presence of amino acid

Test for Type of Compound:

2ml of the extract was treated with 2 ml of dil.ferric chloride solution. Development of green colour indicates the presence of oxyquinalones, pyrocatechol .

PHYSICOCHEMICAL ANALYSIS:

Determination of ph range:

The pH of crude powder in 10 % w/v of water soluble portions of whole plant powder was determined using standard simple glass electrode pH meter.

Determination of moisture content (loss on drying):

This step was done by placing about 1.0 g of whole plant powder, in an accurately weighedmoisture disc. For estimation of loss on drying, it was dried at 105ºC for 3hour in an oven, cooled in a desiccator for 30 minutes and weighed without delay. The loss of weight was calculated as thecontent of in percent of air-dried material.

Determination of total ash:

2 g of air dried coarsely powdered drug was placed in a previously ignited (350ºC for 1 hour) and tarred crucible accurately weighed. Dried material was spread in an even layer in the crucible and the material ignited bygradually increasing the heat to 550ºC for 5 hours in a maffle furnaceuntil it is white, indicating the absence ofcarbon. Cooled in a desiccator and weighed. Total ash content was calculated in mg per g of air-dried material.

Determination of acid insoluble ash:

The ash was washed from the crucible into 100 ml beaker using25 ml of 2N HCl. It was then boiled for 5 min over a Bunsen burner and filtered through an ashless filter paper (Whatman No:42). The residue was washed with hot water twice, ignited to ash, cooledin desiccators and weighed. The residue was weighed and the acidinsoluble ash of the drug was calculated with reference to the air dried sample of crude drug. Acid insoluble ash value is frequently necessary to evaluate thecrude drugs. This ash value indicates contamination with silicaceous material e.g. earth and sand. The comparisonof this with the total ash value of the sample will differentiate between contaminating minerals and variations of the natural ash of the drug.

Determination of water soluble extractive value:

Determination of water soluble extractive value is used for evaluating crude drugs which are not readily estimated by other means. The extracts obtained by exhausting crude drugs are indicative of approximate measure of their chemical constituents. This method is applied to drugs which contain water soluble active constituents of crude drugs such as

tannins, sugars, plant acids, mucilage and glycosides. The water soluble extractive value can be used to indicate poor quality, adulteration with any unwanted material or incorrect processing of the crude drug during the process of drying and storage.

About 5 g of powdered plant material was added to 50 ml of water at 80ºC in a stoppered flask. It was shaken well and allowed to stand for 10 minutes. It was cooled to 15ºC, 2g of kieselghur was added into it and filtered. Transferred 5 ml of the filtrate to a tarred evaporating basin and evaporated on a water bath and the residue was weighed. The percentage of water soluble extractive was calculated with reference to air dried drug.

Determination of alcohol soluble extractive value:

Alcohol is an ideal solvent for extraction of various chemicalslike tannins, resins. Therefore this method is frequently employed to determine the approximate resin content of drug. Generally 90% ethyl alcohol is used for determination of alcohol soluble extracts. Alcohol soluble extracts are one of the tools for standardization of crude drug. Macerated 5 g of dried coarse powder of plant material with100 ml of 90% ethanol in a closed flask for 24 h, shaking frequently during 6h and allowing to stand for 18h. It was filtered immediately taking precaution against loss of alcohol and 25 ml of filtrate wasevaporated to dryness in a tarred flat bottomed shallow dish and dried at 105ºC and weighed. The percentage of alcohol soluble extractive was calculated with reference to air dried drug.

PHARMACOLOGICAL STUDIES:

ANTI DIABETIC ACTIVITY

***In vitro* α-amylase inhibitory activity:**

This study was performed by a modified starch iodine protocol. In short, plant extract or standard of different concentration (10, 20, 40, 80, 160, 320 µg/mL) was taken in prelabeled test tubes. A volume of 20 µL of α-amylase was added to each test tube and incubated for 10 min at 37 °C. After the incubation 200 µL of 1% starch solution was added to each test tube and the mixture was re-incubated for 1 h at 37 °C. Then 200 µL of 1% iodine solution was added to each test tube and after that, 5 mL distilled water was added. Absorbance of the mixture was taken at 565 nm. Blank were undertaken under the same conditions. IC_{50} value was calculated by using regression analysis.

$$\% \ inhibition = \frac{As - Ac}{As} \times 100$$

ANTIOXIDANT ACTIVITY

Abts radical scavenging assay:

A stock solution of ABTS radical cation was prepared by dissolving ABTS (7 mM, 25 mL in deionised water) with potassium persulfate ($K_2S_2O_8$) (140 mM, 440 μL). The mixture was left to stand in the dark at room temperature for 15-16 h (the time required for formation of the radical) before use. For the evaluation of ABTS radical scavenging activity, the working solution was prepared by the previous solution and diluting it in ethanol to obtain the absorbency of 0.700 ± 0.02 at 734 nm. The standard and test sample (5, 10, 20, 40, 80, 160μg) at different concentrations were mixed with the ABTS working solution (1.8 mL) and the reaction mixture was allowed to stand at room temperature for 20 min, then the absorbance was measured by using a UV-visible spectrophotometer at 734 nm. The radical scavenging activity is given as ABTS radical scavenging effect that is calculated by equation:

ABTS radical scavenging effect (%) = [(A0-A1)/A0] × 100

SAFETY STUDIES:

The experimental studies on animals were conducted at Animal house, National Institute of siddha

Objective

The objective of "Acute oral Toxicity Study of ***Marutham pattai kudineer***on Female Wistar rats was to measure the toxicological studies of the drug when treated as a single dose. Animal should be observed for 14 days after the drug administration.

Test Guideline Followed:

Acute toxicity was conducted as per OECD- 423 Guideline with slight modification.

Materials and Methods:

The study was conducted on Female wistar rats. These animals were selected because of the recommended rodent species for oral studies as per followed guideline Female wistar rats, 8-12 weeks old, 140-160gm body weight were used for the study. The body weight range should be within ± 20% of the mean body weight at the time of Randomization and grouping. The rats were purchased from TANUVAS, Madhavaram, Chennai and housed in standard laboratory condition in Polypropylene cages, provided with food water *adlibitum.*

Acclimatization:

The animals were selected after veterinary examination by the veterinarian; selected rats were kept under acclimatization for a week.

Randomization & grouping:

After acclimatization, Rats were randomized as control and treated group. Control group received distilled water and the treatment group was administered with ***Marutham pattai kudineer*** 2gms/kg bwt. was a single dose p.o.

Identification:

Animals were housed with appropriate identification by colouring the fur with picric acid solution prepared in water and with cage cards.

Dose Preparation:

The dose was prepared of a required concentration before dosing by dissolving, in distilled water.

Administration:

The test drug***Marutham pattai kudineer***was administered orally to each female wistar rats as single dose using a needle fitted on to a disposable syringe of appropriate size.

Observation period:

After drug administration observations were started to be recorded at the ½ hr, 1hour, 2hours, 4 hours on day one of dosing and twice daily after that for the next 13 consecutive days. At the 14th day, sensory reactivity to stimuli of different types was conducted. Auditory stimuli responses were measured by clicker sound from approximately 30 cm to the rats; visual stimuli response were measured with the help of shining pen light

in the eye of rats and placing a blunt object near to the eye of rats. Response to proprioceptive stimuli was measured by placing anterior/dorsal surface of animals paw to the table edge. The responses of reactions for these three exercises were normal in animals belonging to both the controls as well as drug treatment dose groups. On day 15, the overnight fasted animals (water allowed *ad libitum*) were sacrificed and examine for gross pathological changes in the major internal organs.

Body Weight:

Individual weights of animals were determined ***Marutham pattai kudineer***before administration, weekly thereafter and at 14 days.

Food Consumption:

The quantity of feed was accessible based on the requirement to the group of animal housed in each cage (3 rats) and the same was record. The leftover of the feed was calculated weekly once. The feed consumed /3 animals /cage /week were calculated by subtraction of left over from total quantity of feed offered during that week.

Sacrifice and macroscopic examination:

At the end of study period, the overnight fasted (water *ad libitum*) animals were anaesthetized with ketamine, the animals in control and ***Marutham pattai kudineer***treated group were sacrificed on 15th day and gross pathological changes were observed in the experimental animals

Statistical analysis:

Values are expressed as mean ± SD. Statistical significance (p) calculated by one way ANOVA followed by dunnett‟s. $P< 0.05$ considered as significant by comparing treated group with control group using Graph Pad Prism 3.

REPEATED DOSE 90-DAYS ORAL TOXICITY STUDY:

Objective:

Repeated dose 90-days oral toxicity studywas conducted as per OECD-408 Guideline. Animals should be observed for 90 days during the***Marutham pattai kudineer***administration. The 90 days study provides information on the possible health

hazard likely to raise from repeated exposure over a prolonged period of time covering post-weaning maturation and growth well into adulthood.

MATERIALS AND METHODS

Test System Detail

Young adult wistar rats of 8-12 weeks old weighing 140-160 gms of both the sex was used for study. The body weight range should be within ± 20% of the mean body weight at the time of Randomization and grouping. Animals were housed in four groups (5/cage/sex) in polypropylene cages in a well-ventilated room under a temperature of 22 ± 3°C and 30 - 70% relative humidity, with a 12-hr light/dark artificial light cycle. The rats were purchased from TANUVAS, Madhavaram, Chennai and housed in standard laboratory condition in Polypropylene cages, provided with food water *adlibitum*

Acclimatization

The animals were selected after veterinary examination by the veterinarian. All the selected animals were kept under acclimatization for a week.

Randomization & grouping:

One day before the initiation of treatment (last day of acclimatization), the selected animals were randomly grouped into six different groups containing 10 male animals and 10 female animals per group.

Numbering and Identification:

Animals were housed with appropriate identification by colouring the fur with picric acid solution prepared in water and with cage cards. The group no., cage no., sex of the animal and animal no. were identified as indicated below using cage label and body marking on the animals

Numbering and Identification of animals in repeated dose 90-days oral toxicity study

CAGE NO	GROUP NO	ANIMAL	SEX
1	I CONTROL	1-10 10-20	MALE FEMALE
2	II LOWDOSE	21-30 31-40	MALE FEMALE
3	III MID DOSE	41-50 51-60	MALE FEMALE
4	IV HIGH DOSE	61-70 71-80	MALE FEMALE

Dose level repeated dose 90-days oral toxicity study:

TEST GROUP	DOSE TO ANIMALS (mg/ kg.b.wt)	NO.OF ANIMALS
GROUP I	Control distilled water(10ml/kg.b.wt)	20 (10male and 10female)
GROUP II	900mg /kg.bwt	20 (10male and 10female)
GROUP III	1800 mg /kg.bwt	20 (10male and 10female)
GROUP IV	3600 mg /kg.bwt	20 (10male and 10female)

Dose Preparation:

*Marutham pattai kudineer*was prepared at the calculated dose of a required concentration.

Administration:

The test drug was administered orally to each rat as single dose using a needle fitted onto a disposable syringe of appropriate size at the following different doses. The concentration was adjusted according to its body weight; the volume not exceeding 10 ml/kg body weight. Variability in test volume was minimized by adjusting the concentration to make sure a constant volume at all dose levels.

Observations:

The observations included but were not restricted to changes in skin and the eyes and mucous membranes and in the respiratory, circulatory, central and autonomous nervous systems and behaviour.

Clinical signs of toxicity:

All the rats were observed at least two times daily with the purpose of recording any symptoms of ill- health or behavioural changes and clinical signs of toxicity daily for 90 days.

Food and water intake:

A measured amount of feed was kept in the cages and then after 24 hrs. the left out amount of feed was measured to calculate the amount of food consumed by the rats. Water intake was observed by visual observation during the Study. In addition, the water consumption in each cage was observed daily for a period of 90 days

Body weight:

The body weight of rats were recorded one week before the start of treatment, and during the course of the treatment on day one, 7^{th}, 14^{th}, 21^{st}, 28^{th},35^{th} ,42^{nd},49^{th},56^{th}, 63rd 70^{th}, 77^{th},84^{th}, 90^{th}day (day of sacrifice)

Pre-terminal deaths:

All rats were observed twice daily for any pre terminal deaths.

Blood Collection:

Blood was collected through retro-orbital sinus from all the animals of four groups on 90th day. The blood was collected in tubes containing as an anticoagulant (Heparin/EDTA). Animals were fasted overnight prior to the blood collection.

Laboratory studies:

During the last day of treatment, blood were withdrawn from the orbital sinus of animals from each group, under thiopental sodium anaesthesia. The collected blood samples also centrifuged 10000 rpm in 10 minutes to separate the serum. The separated serum used to evaluate biochemical parameters like SGOT, SGPT, ALP and BILIRUBIN etc. The

following hematological parameters were analysed (Autoanalyser) Haemoglobin (g %) Packed Cell Volume, White Blood Corpuscles (x103/cmm), Red Blood Corpuscles (x106/cmm) Blood Platelet count (x103/cmm) Differential WBC count.

The following clinical Bio parameters were analysed using Auto analyser. Total serum protein (g/dl), Alanine amino transferase (U/L), Aspartate amino transferase (U/L) Alkaline serum phosphatase (U/L), Cholesterol (mg/dL) Triglyceride

Sacrifice and macroscopic examination:

At the end of study period, the overnight fasted animals were anaesthetized with thiopental sodium and blood samples were collected from retro-orbital sinus. After blood collection, the animals in group 1 to 4 were sacrificed on 90th day.

Histopathology:

The target organs from control and drug treated animals were preserved in 10 % buffered neutral formalin for histopathological examination. Control and highest dose animals will be initially subjected to histopathological investigation. If any abnormality was found in the highest dose group, then the low and mid group will also be examined. All deviations from normal histology were recorded and compared with corresponding controls.

Statistical analysis:

Values are expressed as mean ± SDStatistical significance (p) calculated by one way ANOVA followed by dunnett‟ s. $P< 0.05$ considered as significant by comparing treated group with control groupusing Graph Pad Prism 3.0

CLINICAL STUDY:

Clinical trial Approval & Registration:

The Clinical trial was approved by the Institutional Ethics Committee (IEC) of National Institute of Siddha, Chennai 47 (NIS/IEC/2016/11-09 Date. 14.10.2016) and further registered in Clinical Trial Registry of India (REG NO.CTRI/2018/04/013163)

Study Centre:

Clinical study was conducted at Ayothidoss Pandithar Siddha Hospital, National Institute of Siddha (NIS), Tambaram Sanatorium, Chennai - 47. Necessary permission was obtained from the Administrative head to conduct the study.

SUBJECT SELECTION:

As and when patients with symptoms of inclusion criteria reporting at OPD Aythidoss pandithar hospital of NIS will be subjected to screening test & documentation will be done using screening proforma.

INCLUSION CRITERIA

- Age : 35-65 years
- Sex : Both Males and Females

With symptoms of

- Polyuria
- Polydipsia
- Nocturia
- Polyphagia
- Blood glucose level:
    - Fasting plasma blood glucose level-≤ 150 mg/dl
    - Two Hours postprandial plasma blood glucose level- ≤250 mg/dl
    - Glycosylated haemoglobin (HbA1c) ≤ 8%
- Non-Insulin Dependent Diabetes Mellitus
- Patient willing to give blood and urine sample before and after the treatment
- Willing to participate in Study and signing consent by fulfilling the condition of Proforma.

EXCLUSION CRITERIA

- Fasting plasma blood glucose level- >151 mg/dl
- 2 Hours postprandial plasma blood glucose level- >251 mg/dl
- Glycosylated haemoglobin (HbA1c)- > 8.1%
- Patient with diabetic complications diabetic foot, retinopathy etc.,
- Insulin Dependent Diabetes Mellitus
- Any other serious Systemic Diseases
- Pregnancy and lactation

WITHDRAWL CRITERIA

- Reluctant to continue the study
- Poor patient compliance &defaulters
- Increase in severity of symptoms

TEST & ASSESSMENTS

1. CLINICAL ASSESSMENT

2. SIDDHA ASSESSMENT

3. ROUTINE INVESTIGATION

4. SPECIFIC INVESTIGATION

1. CLINICAL ASSESSMENT

- Increased frequency of Urination (polyuria)
- Thirst (polydipsia)
- Excessive hunger (polyphagia)
- Body pain Tiredness
- Burning feet
- Generalized/genital pruritis

2. SIIDDHA ASSESSMENT

Enn Vagai Thervu (Eight types of Examination):

1. Nadi (Pulse perception)
2. Naa (Tongue)
3. Niram (Complexion)
4. Mozhi (Voice)
5. Vizhi (Eyes)
6. Parisam (Palpatory perception)
7. Malam (Bowel habits)
8. Moothiram (Urine){Neerkuri& Neikuri}

3. ROUTINE INVESTIGATION HAEMATOLOGY

- Hb (gms%)
- Total WBC Count(cells/cumm)
- DC

  Polymorphs(%)

Lymphocytes (%)

Eosinophils (%)

Monocytes (%)

Basophils (%)

- Total RBC count (cells/cu.mm)
- ESR(mm/hr)

CLINICAL BIOCHEMISTRY

RENAL FUNCTION TEST

- Blood urea (mg/dl)
- S. total creatinine (mg/dl)
- Uric acid (mg/dl)

LIPID PROFILE

- S. Total cholesterol (mg/dl)
- HDL (mg/dl) ,sLDL (mg/dl) ,VLDL (mg/dl) ,TGL (mg/dl)

LIVER FUNCTION TEST

- S. Total bilirubin (mg/dl)
- S. Direct bilirubin (mg/dl)
- S. Indirect bilirubin (mg/dl)
- SGOT (U/dl)
- SGPT (U/dl)
- S. Alkaline phosphatase (U/dl)

URINE EXAMINATION

- Neerkuri and Neikuri
- Albumin
- Sugar (Fasting & postprandial)
- Deposits

4. SPECIFIC INVESTIGATION

HbA1C (> 6)

ENROLLMENT OF THE PATIENTS:

In this clinical trial, patients reporting at NIS OPD with the clinical symptoms of Polyuria, Polydipsia, Polyphagia, General body pain and tiredness were examined clinically for enrolling in the study based on the inclusion and exclusion criteria. The enrolled patients were informed about the study, trial drug, possible outcomes and the objectives of the study in the language and terms understandable to them and getting consent in the Informed consent form.

All the patients were given unique registration card in which there would be patient's registration number of the study, Address, Phone number and Doctors phone number etc. so as to report easily whenever any complication arises. Complete clinical history, complaints and duration, examination findings were recorded in the prescribed Proforma.Patients were advised to take the trial drug and appropriate dietary advice.

CONDUCT OF THE STUDY:

The trial drug "Maruthampattai kudineer" was given for 90 days. OPD patients were requested to visit the hospital once in 7 days. In each and every visit clinical assessment and prognosis were recorded. Laboratory investigations were done on the first day and also at the end of the trial. Defaulters for more than three days would not be allowed to continue and would be withdrawn from the study with fresh cases being inducted. OP Patients were requested to visit the hospital once in 7 days.At each visit clinical assessment was done and prognosis noted. The Laboratory Investigation was done on the 0 day and 91st day of the trial. At the end of the treatment, the patients were advised to visit the OPD for further 3 months for follow-up. Patients were advised to practice asanas in empty stomach after evacuation of urine and motion for 45-60 minutes every morning. Asanas were taught to the patients during their each visit to the OPD. Under my guidance, the patients were asked to do the recommended pattern of asanams at NIS *yogam* hall on their each visit . Patients were motivated to practise asanas regularly for their well-being even after the study.

If any trial patient who fails to collect the trial drug on the prescribed day but wants to continue in the trial from the next day or two, he/she will be allowed, but defaulters of one week and more will not be allowed to continue and be withdrawn from the study with fresh case being inducted.

ADVERSE/SERIOUS EFFECTS MANAGEMENT:

If the study patient develops any inconveniences, he/she was immediately withdrawn from the study. It will also be reported to the Institutional Ethical Committee member of NIS.

OUTCOME

The changes in plasma blood glucose level by using Blood Investigations before and after the treatment were observed

1. Fasting blood glucose level
2. Postprandial blood glucose level
3. HbA1C

ETHICAL ISSUES:

1. To prevent any infection, while collecting blood sample from the patient, only disposable syringes, disposable gloves, with proper sterilization of lab equipment's were used.
2. The data collected from the patient is kept confidently. The patient was informed about the diagnosis, treatment and follow- up.
3. After the consent of the patient (through consent form) they were enrolled in the study.
4. Informed consent was obtained from the patient explaining in the understandable to the patient.

DATA COLLECTION FORMS:

- FORM l Screening & selection proforma
- FORM lI Case record form
- FORM llI Laboratory parameters chart
- FORM lV Drug compliance form
- FORM V Information sheet
- FORM VI Consent form
- FORM VII Withdrawal form/ adverse drugReaction/ pharmacovigilance form
- FORM VIII Dietary advice form

Authentication of the ingredients:

The herbal ingredients of *Maruthampattai kudineer* were identified and authenticated by the Medicinal Botanist of NIS **(certificate number: NISMB2902017)**.

Purification of ingredients:

The raw drugs were purified as per the methods mentioned in the Siddha literatures. After purification, the ingredients are dried in the shade.

Preparation of *Maruthampattai kudineer*:

The raw drugs are made into a coarse powder.

RESULTS OF BIOCHEMICAL ANALYSIS:

Results of Acid radicals studies

S.NO	Parameter	Observation	Result
1	Test for Sulphate	Cloudy appearance Present	Positive
2	Test for Chloride	-	Negative
3	Test For Phosphate	Cloudy yellow appearance present	Positive
4	Test For Carbonate	Cloudy appearance Present	Positive
5	Test For Nitrate	-	Negative
6	Test for Sulphide	-	Negative
7	Test For Fluoride &oxalate	-	Negative
8	Test For Nitrite	-	Negative
9	Test For Borax	-	Negative

Interpretation

The acidic radicals test shows the presence of **Sulphate, phosphate, carbonate.**

Results of basic radicals studies:

S.NO	Parameter	Observation	Result
1	Test for Lead	-	Negative
2	Test for Copper	-	Negative
3	Test For Aluminium.	-	Negative
	Test For Iron.	-	Negative
5	Test For Zinc	-	Negative
6	Test for Calcium	Cloudy appearance and white precipitate present	Positive
7	Test For Magnesium	-	Negative
8	Test For Ammonium	-	Negative
9	Test For Potassium	-	Negative
10	Test For Sodium	-	Negative
11	Test For Mercury	-	Negative
12	Test For Arsenic	-	Negative

Interpretation

The basic radical test shows the presence of **Calcium**and absence of heavy metals such as Lead, Iron, Arsenic and Mercury.

Test for phytochemicals:

S.NO	Parameter	Observation	Result
1	Test for Starch	-	Negative
2	Test for Reducing sugars	-	Negative
3	Test For Alkaloids	Yellow colour developed	Positive
4	Test For Tannic acid .	Blue-black precipitate obtained	Positive
5	Test for unsaturated compounds	-	Negative
6	Test for Amino acid	-	Negative
7	Test For Type of compounds	Green colour developed	Oxyquinalone, epinephrine and pyro catechol

Interpretation

The Miscellaneous test shows the presence of **Alkaloids, Tannic acid, Oxyquinalone,epinephrine and pyro catechol**

RESULTS OF PHSICOCHEMICAL ANALYSIS

Organoleptic characters:

Colour : Brown.

Odour : Pleasant.

Taste : Astringent.

Consistency : Coarse powder

S.No	Physicochemical analysis	Results (w/w)
1.	Description	Brownish powder
2.	pH (10 % w/v aq. solution)	**4.96**
3.	Loss on drying at 105°C	**11.58 %**
4.	Total ash	**16.74 %**
5.	Acid-insoluble ash	**0.98 %**
6.	Water-soluble extractive	**24.29 %**
7.	Alcohol soluble extractive	**18.96 %**

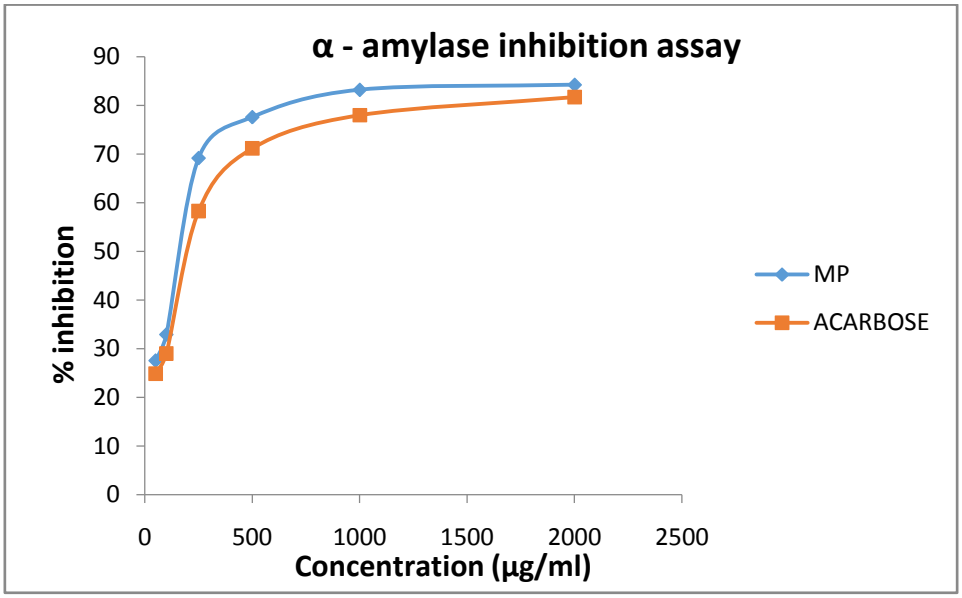
This formulation satisfy the Pharmacopoeia standards and as per the WHO Guidelines.

PHARMACOLOGICAL ACTIVITY:

Anti-diabetic activity:

The finding of inhibitory activity of *Maruthampattai kudineer* is represented in the below table. The IC50 value was 160.017µg/ml for on α-amylase enzyme.The standard drug Acarbose exhibited 50% inhibition on α-amylase enzyme at 58.26 µg/ml.

S.NO	CONC.	MP	ACARBOSE
1	50	27.5147929	24.84662577
2	100	32.87671233	28.98550725
3	250	69.14357683	58.26235094
4	500	77.56410256	71.14252061
5	1000	83.17307692	77.9676259
6	2000	84.20373952	81.68908819

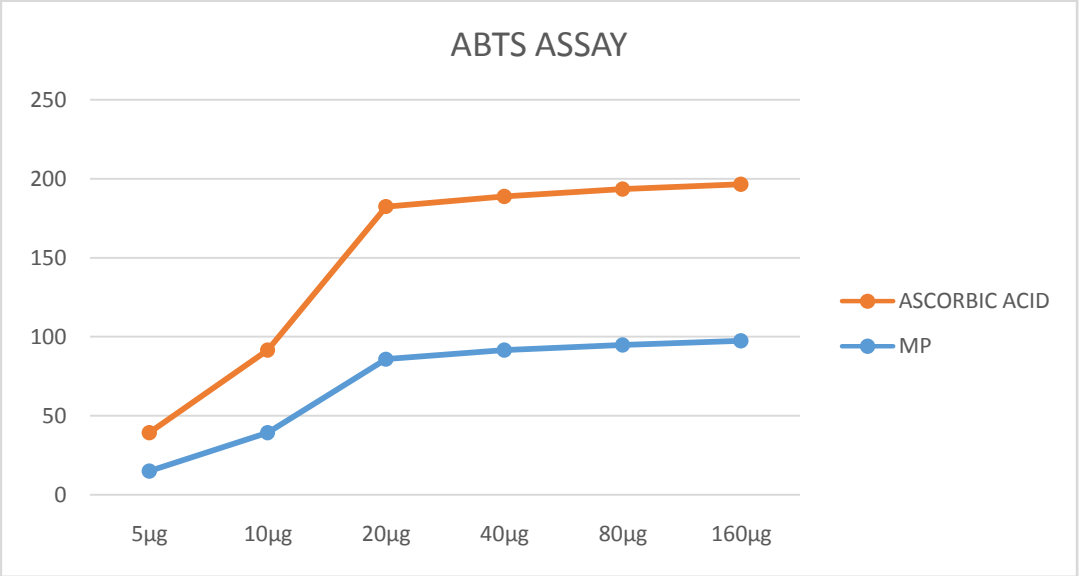


Antioxidant activity:

ABTS assay

The IC_{50} value of *Maruthampattai kudineer* (MP) was **12.02** and the standard drug (Ascorbic acid) was **7.53**

CONC.	MP	ASCORBIC ACID
5µg	14.9	24.33
10µg	39.27	52.21
20µg	85.75	96.61
40µg	91.5	97.3
80µg	94.8	98.6
160µg	97.4	99.1



TOXICITY STUDY

Acute toxicity

Maruthampattai kudineerwas administered single time at the dose of 2gms/kg to rats and observed for consecutive 14 days after administration. According to the OECD guideline 423 when there is information in support of non-toxicity or low and immortality nature of the test substance, then the limit test at the dose level 2 gms/kg body weights (highest starting dose level) was conducted. All animals were observed daily once for any abnormal clinical signs. Weekly body weight and food consumption were recorded.

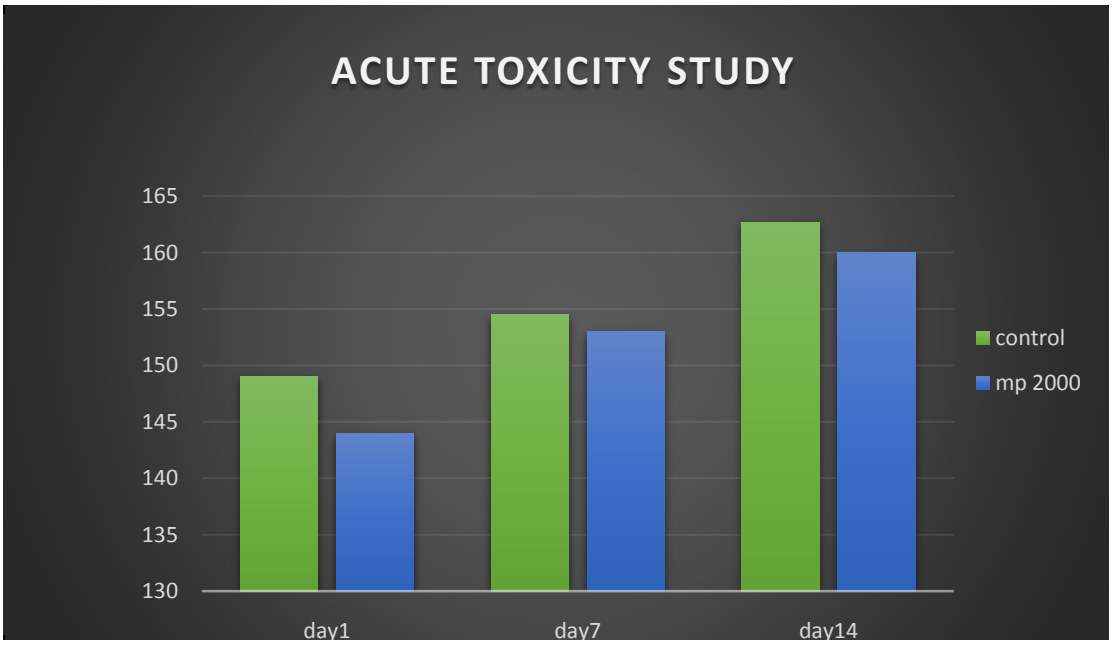
No mortality was observed during the total period of the study. Data obtained in this study indicated no significance physical and behavioural signs of any toxicity due to administration of ***Maruthampattai kudineer***at the dose of 2gms/kg to rats. At the 14th day, all animals were observed for functional and behavioural examination.

In functional and behavioural examination, home cage activity, hand held activity were observed. Home cage activities like Body position, Respiration, involuntary movement, (Clonic and Tonic), Palpebral closure, Approach response, Touch response, Pinna reflex, Sound responses, Tail pinch response were observed. Handheld activities (Reactivity and Handling), Palpebral closure, Lacrimation, Salivation, Piloercetion, Papillary reflex, abdominal tone, Limb tone were observed. Functional and behavioural examination was normal in all groups. Food consumption of all treated animals was found normal as compared to control group. Body weight at weekly interval was measured to find out the effect of ***Marutham pattai kudineer***on the growth rate. No significant body weight changes were observed between control and treatment group. There were no treatment related mortality in both control and treatment groups throughout the experimental period No pathological (gross) changes were observed in the experimental animals

Effect of *Maruthampattai kudineer*on Body weight of Wistar Rats in acute toxicitystudy

TREATMENT	BODY WEIGHT		
	DAY 1	DAY 7	DAY 14
CONTROL	144±.27	154.5±0.45	162.7±0.64
MP (2000mg/kg)	149±0.32	153±0.17	160±0.75

Values are expressed as mean ± SD. Statistical significance (p) calculated by one way ANOVA followed by dunnett's. *P*< 0.05 considered as significant by comparing treated group with control group using Graph Pad Prism.



Clinical Observation of control and *Maruthampattai kudineer*treated experimentalanimals in acute toxicity study

OBSERVATION		**SIGNS**	**OBSERVATION**	**SIGNS**
Lethality		X	Stereotypies(chewing)	X
Convulsion		X	Stereotypies (Head movements)	X
Tremor		X	Head twitches	X
Straub tail		X	Scratching	X
Sedation	#1	X	Respiration	X
	#2	X	Aggressiveness	X
	#3	X	Fear	X
Excitation	#1	X	Reactivity to touch	X
	#2	X	Muscle tone	X
	#3	X	Loss of rightingReflex	X
Abnormal gait(rolling)		X	Ptosis	X
Abnormal gait(tip toe)		X	Exophthalmos	X
Jumps		X	Loss of grasping	X
Motor coordination		X	Akinesia	X
Loss of balance		X	Catalepsy	X
Fore paw treading		X	Loss of traction	X
Writhes		X	Loss of corneal reflex	X
Piloerection		X	Analgesia	X
Salivation		X	Defecation	X
Lacrimation		X	Others	X

X – No sign / √ - Present; Values are expressed as mean ± SD

Gross pathology observations of control and *Marutham pattai kudineer*treated experimental animals

ORGANS	OBSERVATION
Brain	No abnormal lesion observed
Eyes	No abnormal lesion observed
Lymph node	No abnormal lesion observed
Trachea	No abnormal lesion observed
Oesophagus	No abnormal lesion observed
Lungs	No abnormal lesion observed
Heart	No abnormal lesion observed
Brain	No abnormal lesion observed
Liver	No abnormal lesion observed
Stomach	No abnormal lesion observed
Duodenum	No abnormal lesion observed
Small and large intestine	No abnormal lesion observed
Kidney	No abnormal lesion observed
Spleen	No abnormal lesion observed
Sex organs	No abnormal lesion observed
Pancreas	No abnormal lesion observed

REPEATED DOSE 90-DAYS ORAL TOXICITY STUDY

Clinical Signs

No abnormal home cage activities, behavioural responses or neurological symptoms were observed before and after the exposure of *Maruthampattai kudineeer*. All animals in this study were free of toxic clinical signs throughout the dosing period of 90 days.

Mortality:

Since examination of clinical signs plays main role in toxicological testing, mortality and morbidity were recorded two times a day throughout the study. All animals in control and in all the treated dose groups survived during the dosing period of 90 days.

Body weight:

Results of body weight determination of animals from control and different dose groups exhibited comparable body weight gain (throughout the dosing period of 90 days)

Food and water consumption:

Feed and water consumption of *Maruthampattai kudineer*treated groups were found to be in significant in both the sexes when compared to control. The faecal/urinary excretion patterns were also found to be normal in MP administered rats in comparison to the vehicle treated rats.

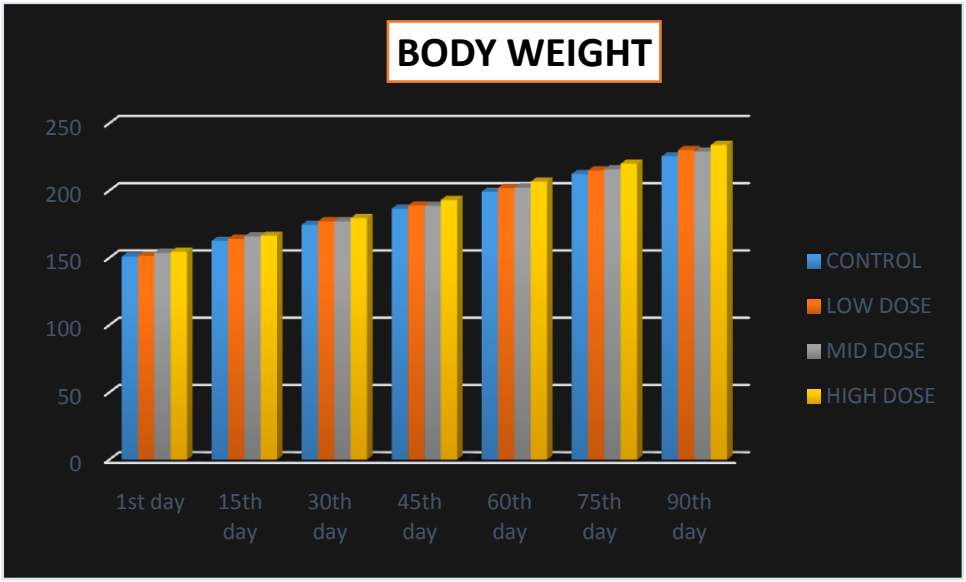
Clinical Observation of control and *Maruthampattai kudineer*treated experimentalanimals in repeated dose 90-days oral toxicity study

OBSERVATION		SIGNS	OBSERVATION	SIGNS
Lethality		X	Stereotypies(chewing)	X
Convulsion		X	Stereotypies (Head movements)	X
Tremor		X	Head twitches	X
Straub tail		X	Scratching	X
Sedation	#1	X	Respiration	X
	#2	X	Aggressiveness	X
	#3	X	Fear	X
Excitation	#1	X	Reactivity to touch	X
	#2	X	Muscle tone	X
	#3	X	Loss of rightingReflex	X
Abnormal gait(rolling)		X	Ptosis	X
Abnormal gait(tip toe)		X	Exophthalmos	X
Jumps		X	Loss of grasping	X
Motor coordination		X	Akinesia	X
Loss of balance		X	Catalepsy	X
Fore paw treading		X	Loss of traction	X
Writhes		X	Loss of corneal reflex	X
Piloerection		X	Analgesia	X
Salivation		X	Defecation	X
Lacrimation		X	Others	X

Effect of *Maruthampattai kudineer*on Body weight of experimental Wistar rats in 90 days repeated oral toxicity study

SL.NO	DAY	CONTROL	LOW DOSE	MID DOSE	HIGH DOS
1.	Initial day	150.9± 6.57	151.5 ± 5.19	153.8 ±5.88	154.5 ± 4.83
2.	15thday	162.6± 6.63	164.1 ± 6.31	166.9 ± 8.10	168.4 ± 6
3.	30thday	174.5 ± 6.91	177.2± 6.35	178.2 ± 9.95	180.5 ± 6.81
4.	45thday	186.5± 7.30	188.9± 6.80	188.7 ± 11.70	192.9 ± 7.60
5.	60thday	199.1± 8.71	201.9 ± 7.59	204.2 ± 13.02	206.6 ±8.01
6.	75thday	212.3± 10.14	214.9± 8.39	216.8 ± 14.06	220 ± 9.11
7.	90thday	225.4± 11.39	230.1 ± 9.26	229 ± 15.43	235.9 ±10.53

Values are expressed as mean ± SD. Statistical significance (p) calculated by one way ANOVA followed by dunnett's. *P*< 0.05 considered as significant by comparing treated group with control group using Graph Pad Prism

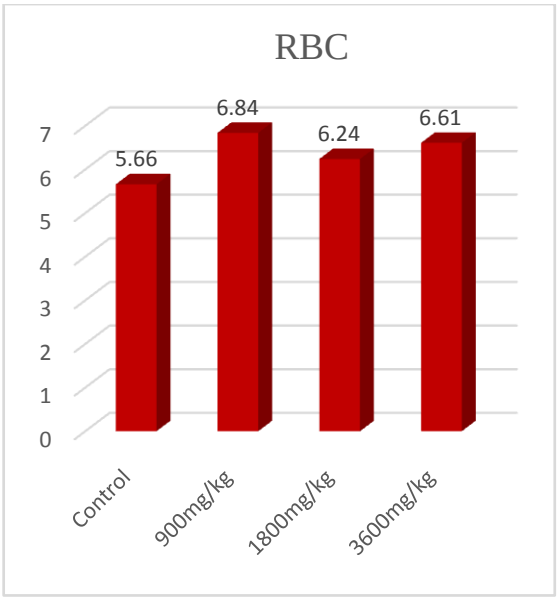


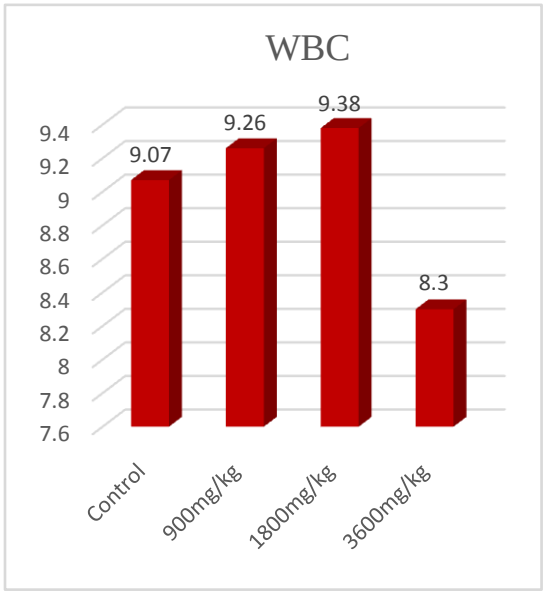
Hematological Investigations:

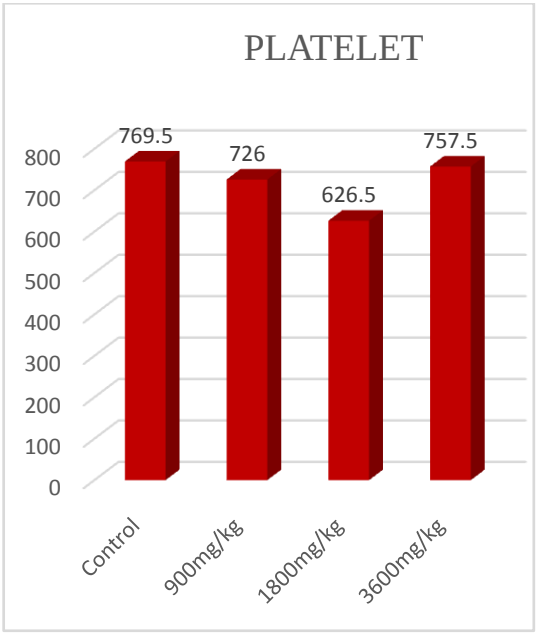
The haemopoietic system serves as vital goal for toxic chemicals and is a susceptible index for pathological conditions both in humans and animals. The results of haematological investigations conducted on day 90 does not reveal any significant changes in the values of various parameters observed when compared with those of respective control.

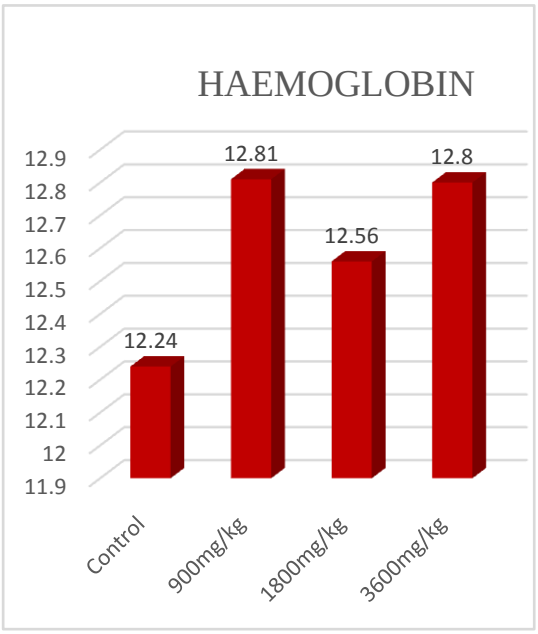
Effect of *Maruthampattai kudineer* of haematological parameters of experimentalWistar rats in 90 days repeated oral toxicity study.

BLOOD PARAMETERS	CONTROL	LOW DOSE	MID DOSE	HIGH DOSE
RBC	5.66±0.34	6.85±0.69	6.24±0.55	6.61±1.11
WBC	9.07±2.17	9.26±2.18	9.38±2.11	8.30±1.5
PLATLET	769.75±80.65	726.6±126.17	626.6±91.55	757.55±110.6
HB	12.12±1.7	12.81±1.63	12.56±1.59	12.85±1.38
T.CHOLESTEROL	108.92±13.4	113.55±18.43	132.54±9.81	129.74±12.86
TGL	49.35±5.1	40.25±7.9	40.65±8.06	38.5±10.88
CREATININE	0.58±0.19	0.72±0.16	0.69±0.21	0.68±0.21
SGOT	88.2±7.14	90.35±20.5	92.15±23.30	95.45±16.28
SGPT	28.85±7.43	30.85±8.02	37±9.13	32.35±8.96
T.BILIRUBIN	0.35±0.16	0.51±0.36	0.44±0.25	0.93±1.08


RBC
7
6
5
4
3
2
1
0
5.66
6.84
6.24
6.61
Control
900mg/kg
1800mg/kg
3600mg/kg


WBC
9.4
9.2
9
8.8
8.6
8.4
8.2
8
7.8
7.6
9.07
9.26
9.38
8.3
Control
900mg/kg
1800mg/kg
3600mg/kg


PLATELET
800
700
600
500
400
300
200
100
0
769.5
726
626.5
757.5
Control
900mg/kg
1800mg/kg
3600mg/kg


HAEMOGLOBIN
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12.8
12.7
12.6
12.5
12.4
12.3
12.2
12.1
12
11.9
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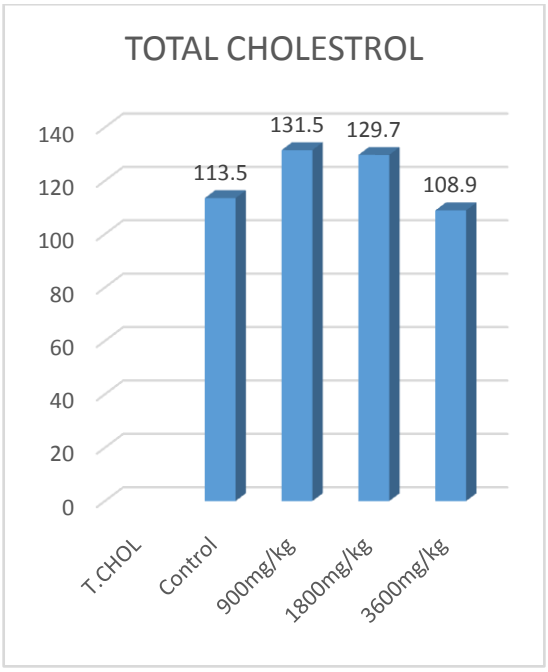
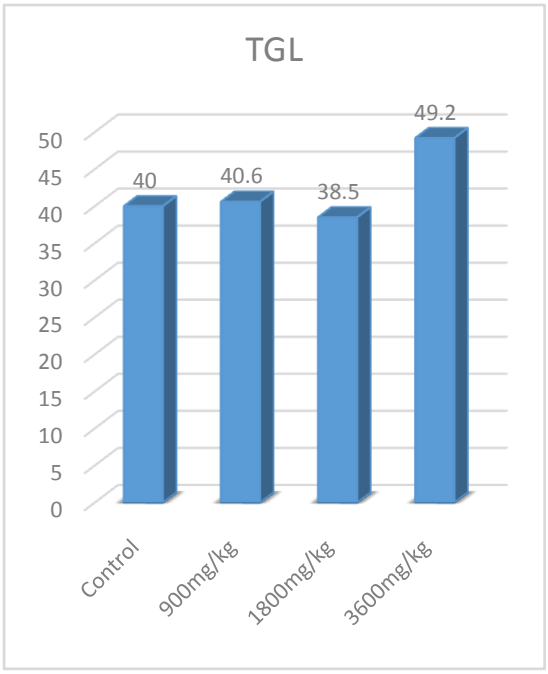
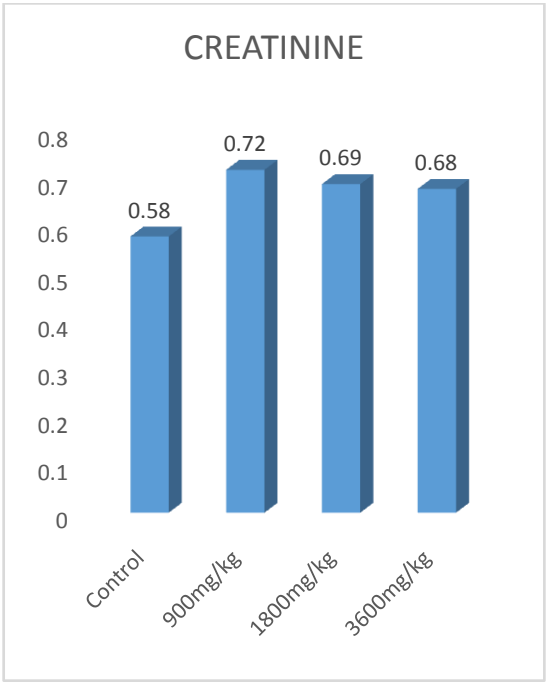
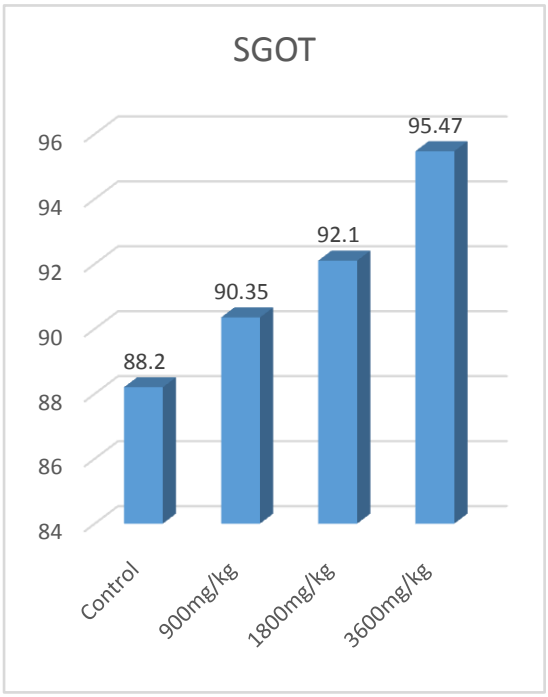
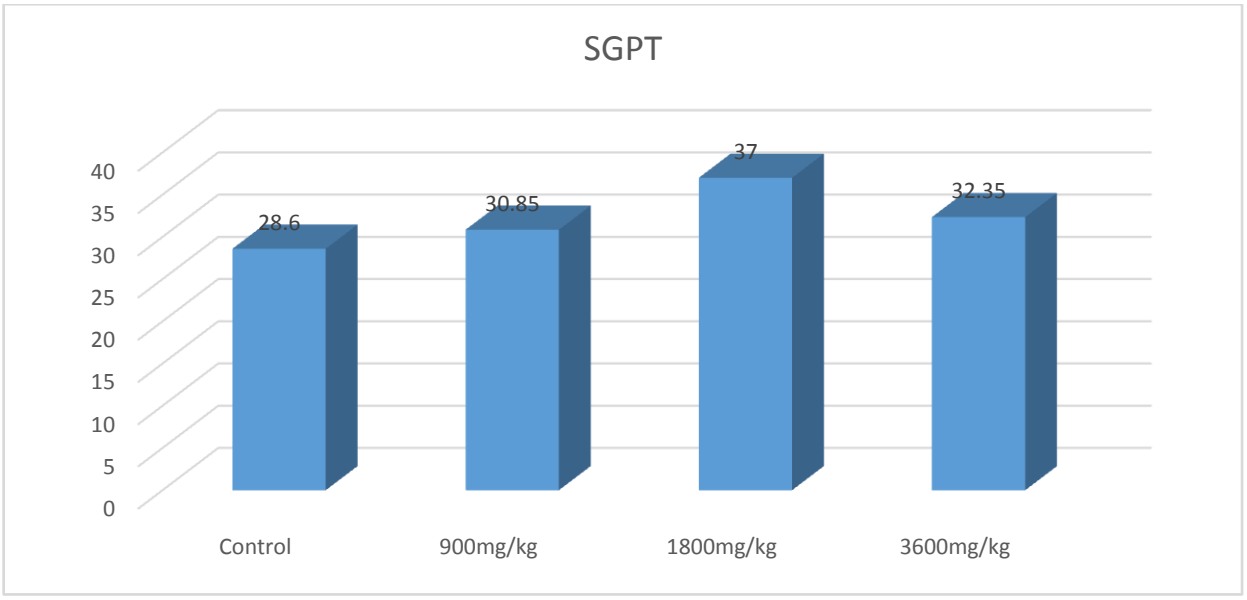
12.8
Control
900mg/kg
1800mg/kg
3600mg/kg

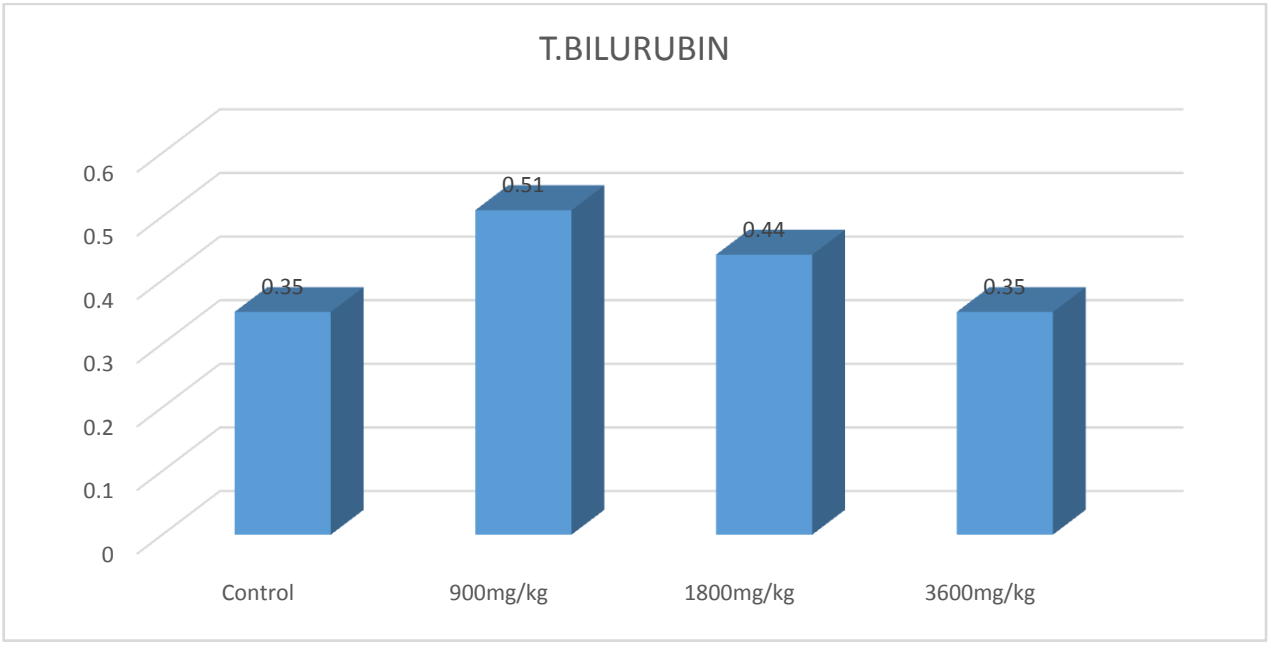

TOTAL CHOLESTROL
140
120
100
80
60
40
20
0
113.5
131.5
129.7
108.9
T.CHOL
Control
900mg/kg
1800mg/kg
3600mg/kg


TGL
50
45
40
35
30
25
20
15
10
5
0
40
40.6
38.5
49.2
Control
900mg/kg
1800mg/kg
3600mg/kg


CREATININE
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
0.58
0.72
0.69
0.68
Control
900mg/kg
1800mg/kg
3600mg/kg


SGOT
96
94
92
90
88
86
84
88.2
90.35
92.1
95.47
Control
900mg/kg
1800mg/kg
3600mg/kg

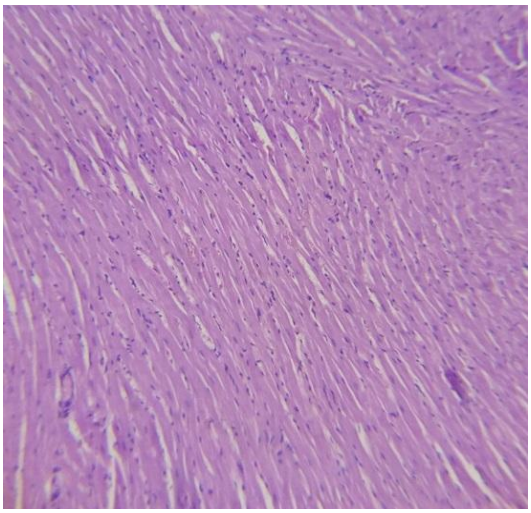

SGPT
40
35
30
25
20
15
10
5
0
28.6
30.85
37
32.35
Control
900mg/kg
1800mg/kg
3600mg/kg


T.BILURUBIN
0.6
0.5
0.4
0.3
0.2
0.1
0
0.35
0.51
0.44
0.35
Control
900mg/kg
1800mg/kg
3600mg/kg

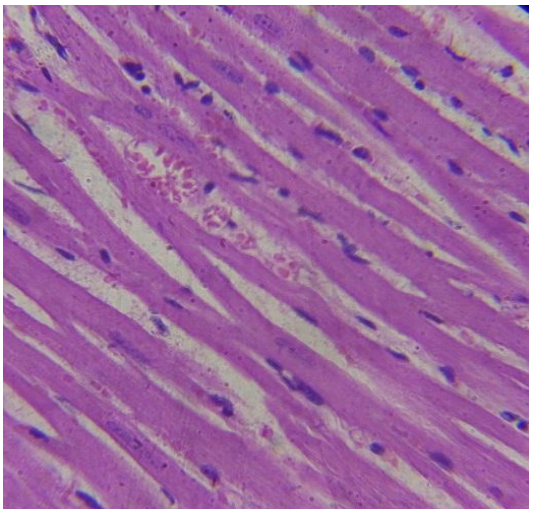
CONTROL MALE

Histopathology of Heart

Low Power Magnification 10X

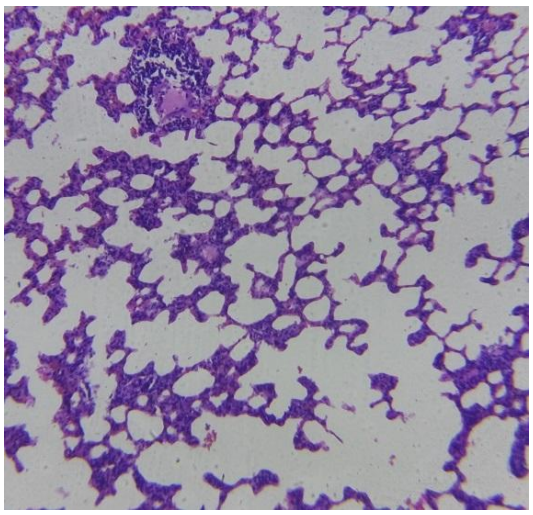


High Power Magnification 40X

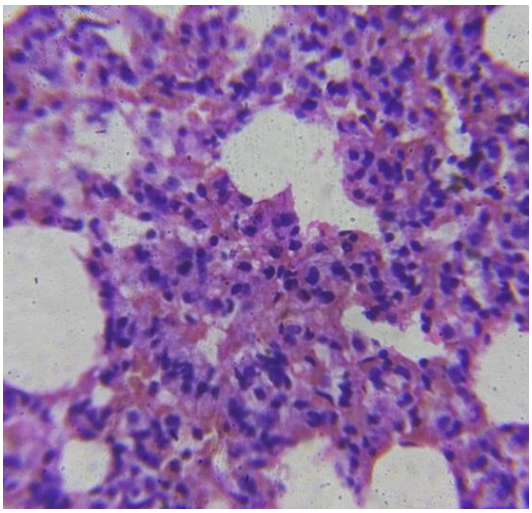


Histopathology of Lung

Low Power Magnification 10X

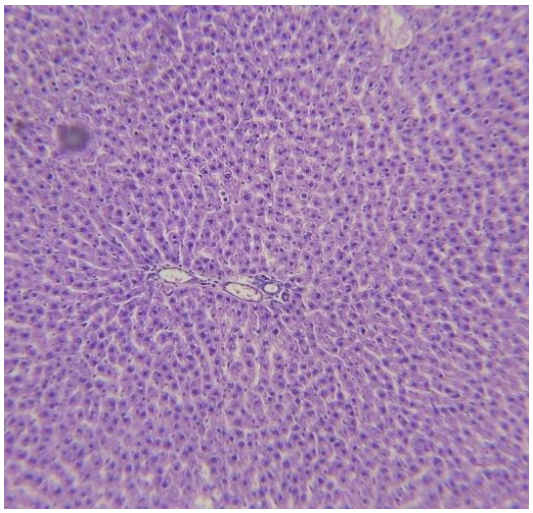


High Power Magnification 40X

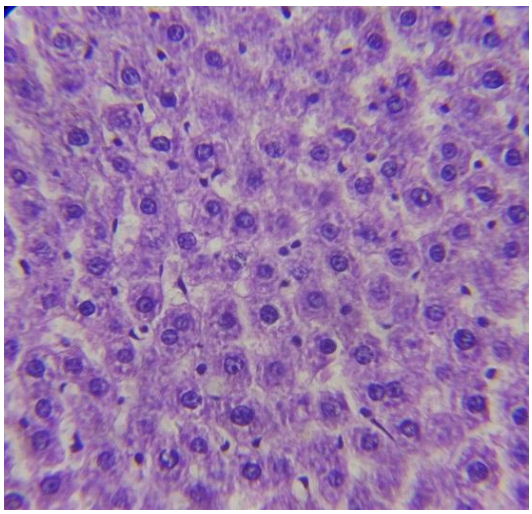


Histopathology of Liver

Low Power Magnification 10X

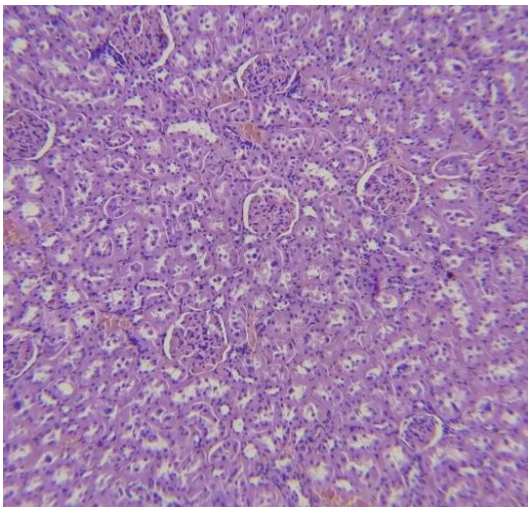


High Power Magnification 40X

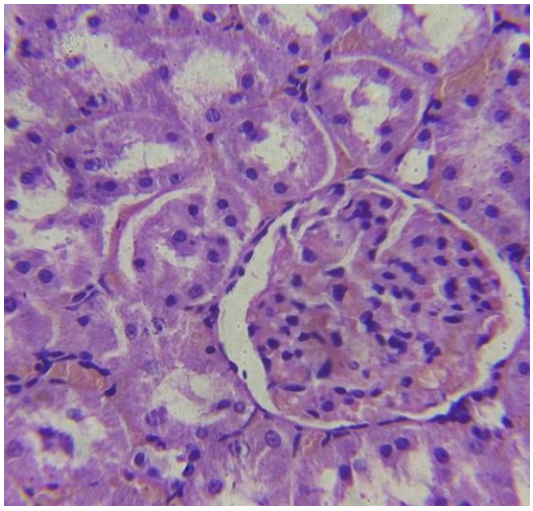


Histopathology of Kidney

Low Power Magnification 10X

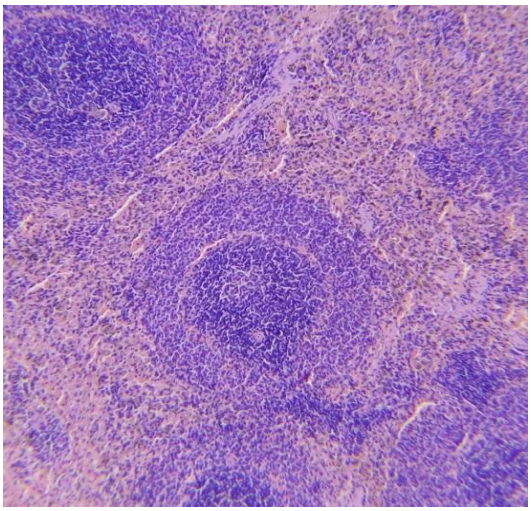


High Power Magnification 40X

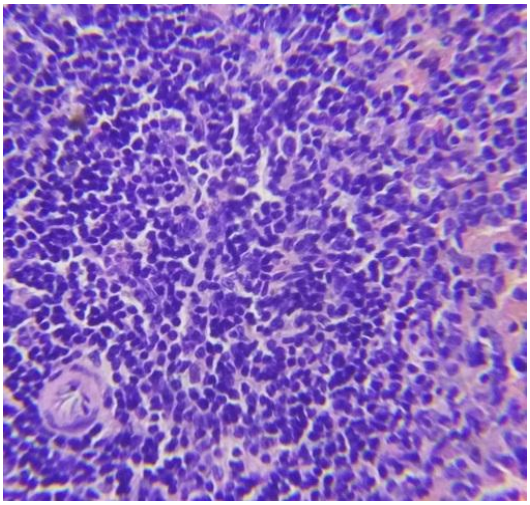


Histopathology of Spleen

Low Power Magnification 10X

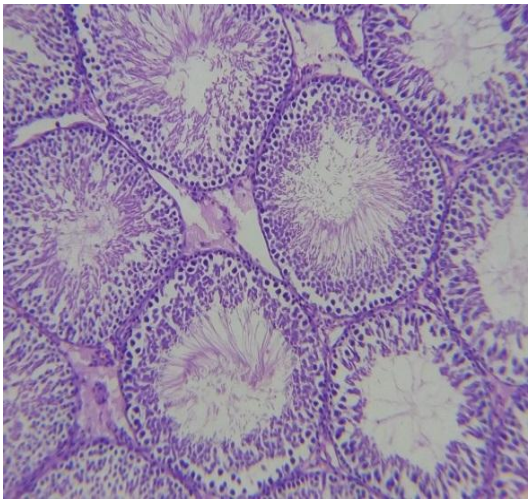


High Power Magnification 40X

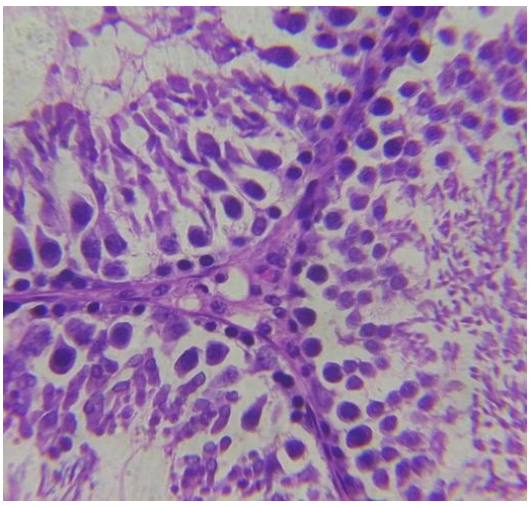


Histopathology of Testes

Low Power Magnification 10X



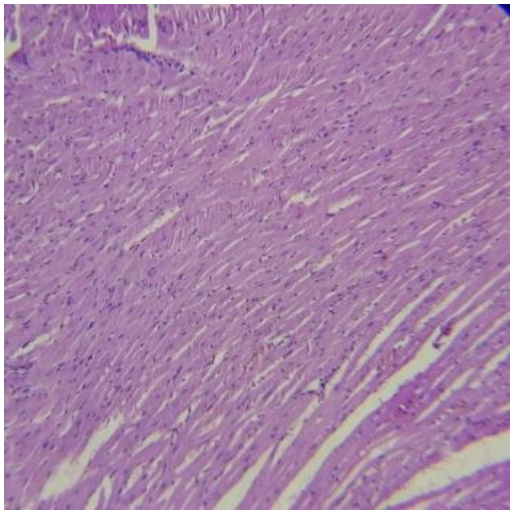
High Power Magnification 40X



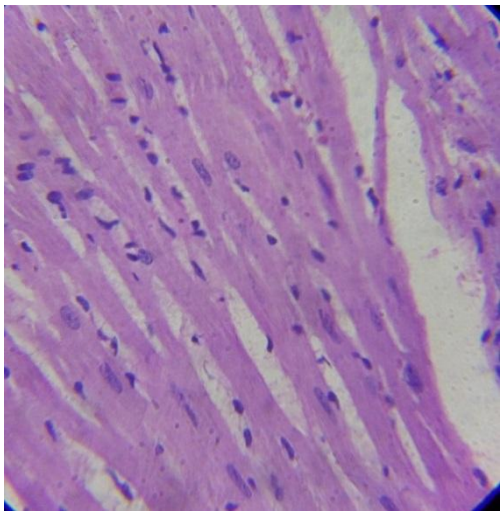
CONTROL FEMALE

Histopathology of Heart

Low Power Magnification 10X

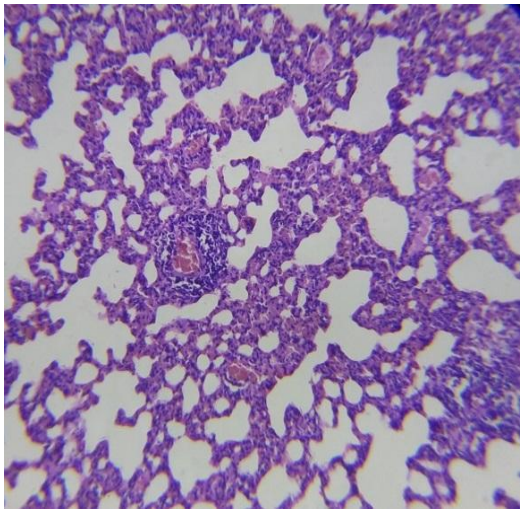


High Power Magnification 40X

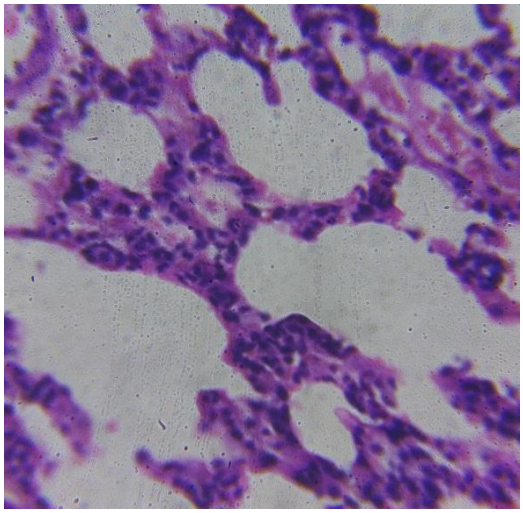


Histopathology of Lung

Low Power Magnification 10X

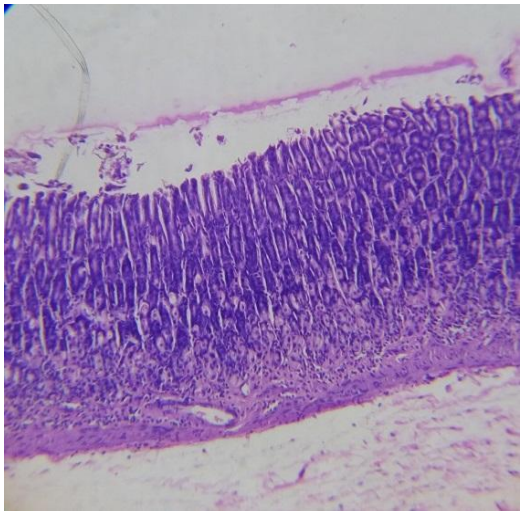


High Power Magnification 40X

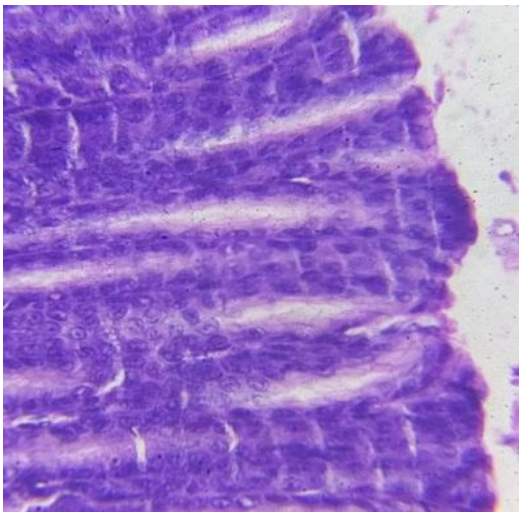


Histopathology of Stomach

Low Power Magnification 10X

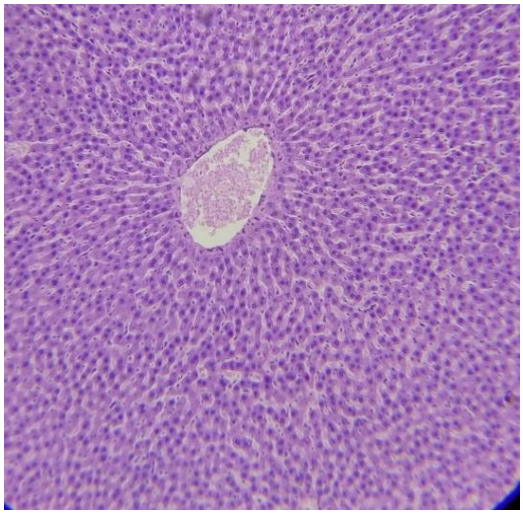


High Power Magnification 40X

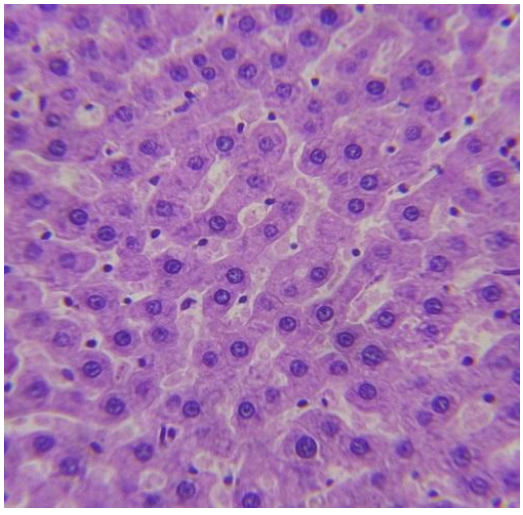


Histopathology of Liver

Low Power Magnification 10X

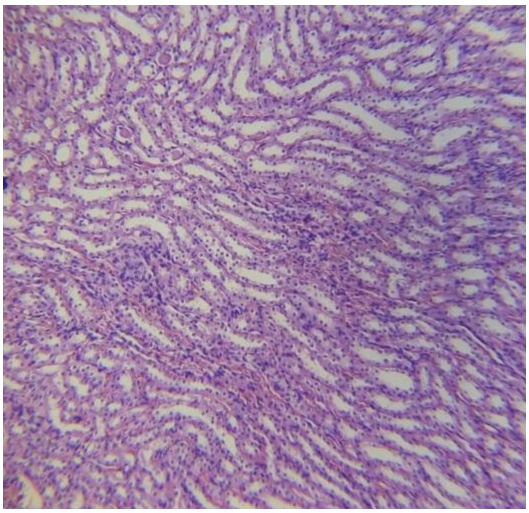


High Power Magnification 40X

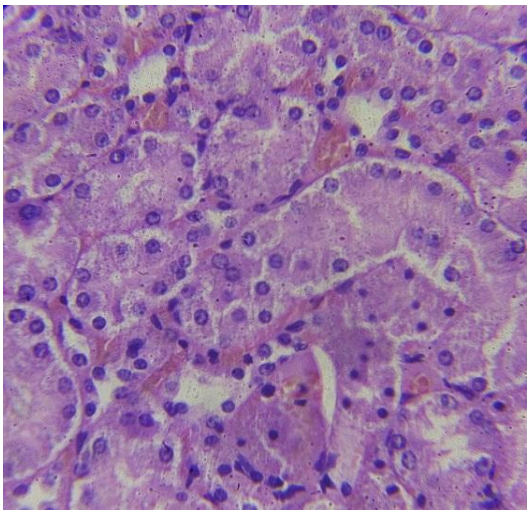


Histopathology of Kidney

Low Power Magnification 10X

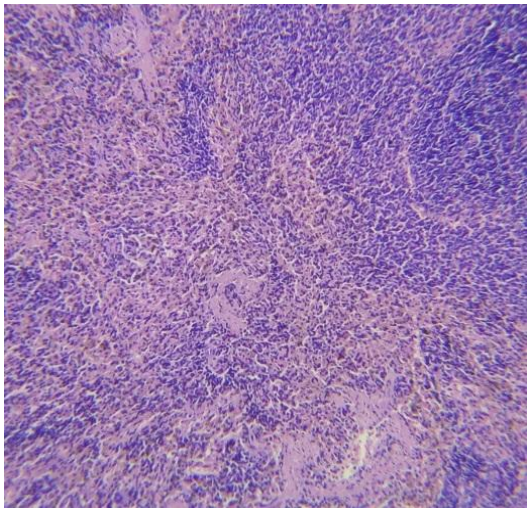


High Power Magnification 40X

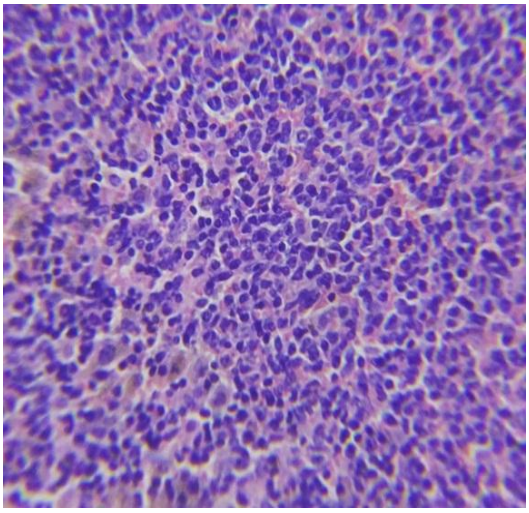


Histopathology of Spleen

Low Power Magnification 10X

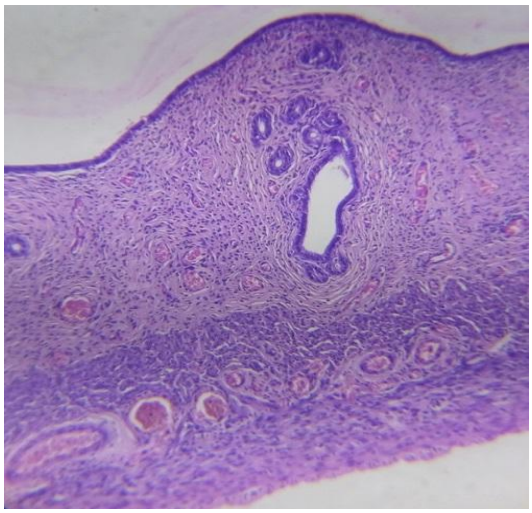


High Power Magnification 40X

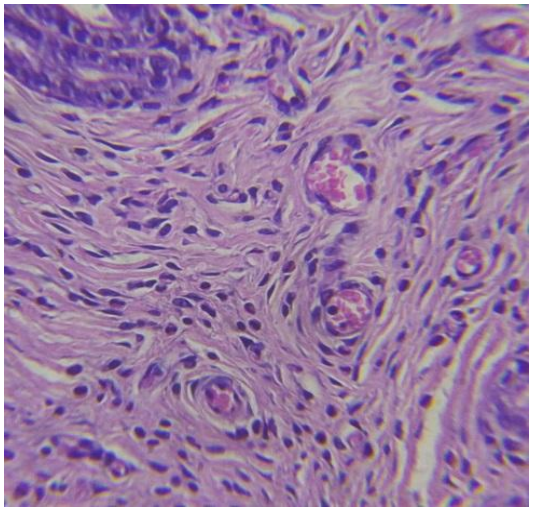


Histopathology of Uterus

Low Power Magnification 10X

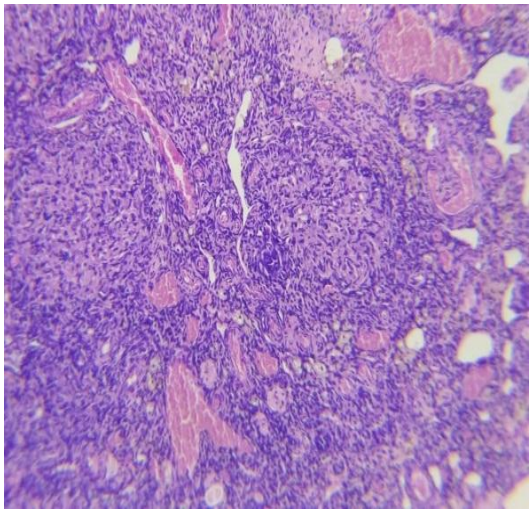


High Power Magnification 40X

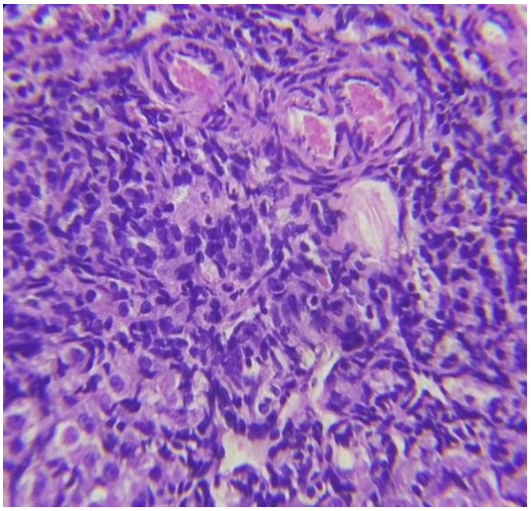


Histopathology of Ovary

Low Power Magnification 10X



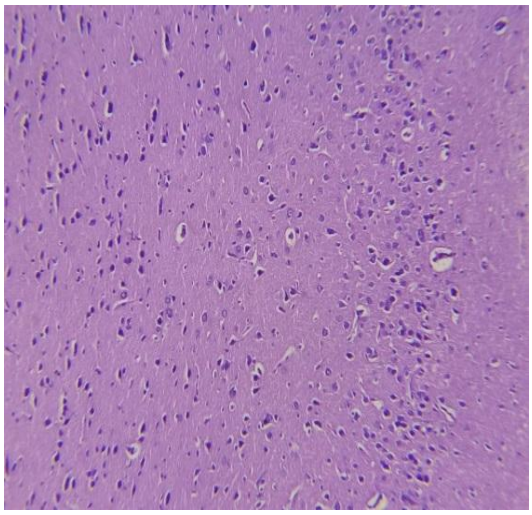
High Power Magnification 40X



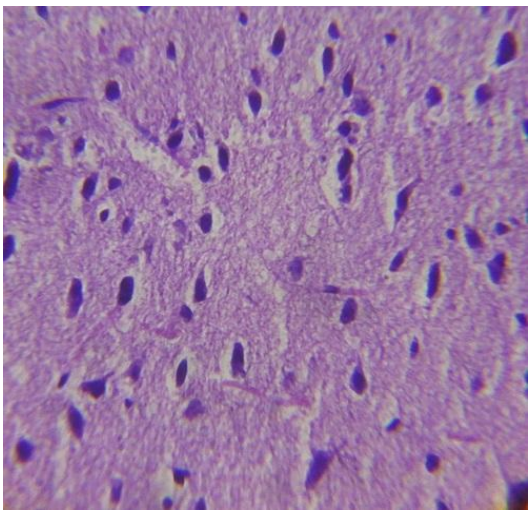
HIGH DOSE- MALE

Histopathology of Brain

Low Power Magnification 10X

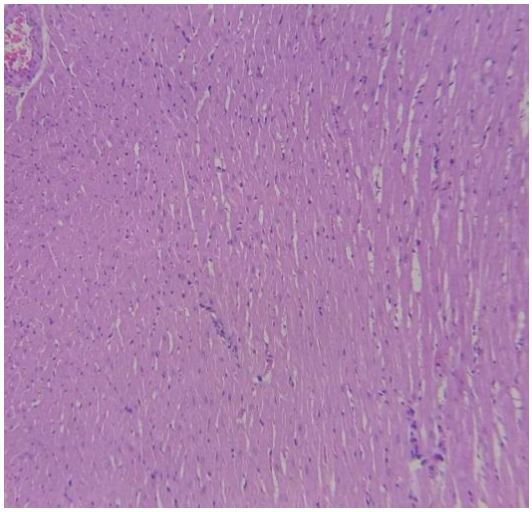


High Power Magnification 40X

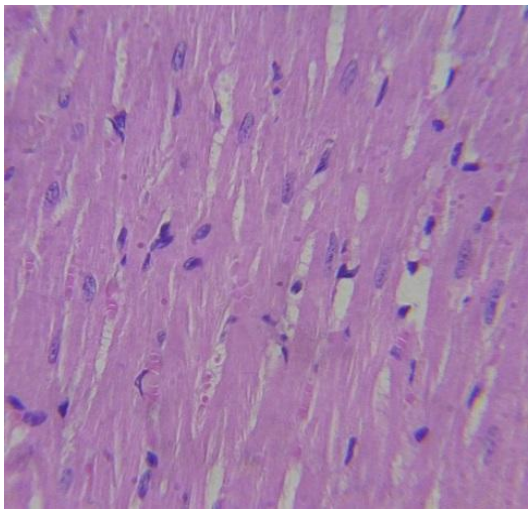


Histopathology of Heart

Low Power Magnification 10X

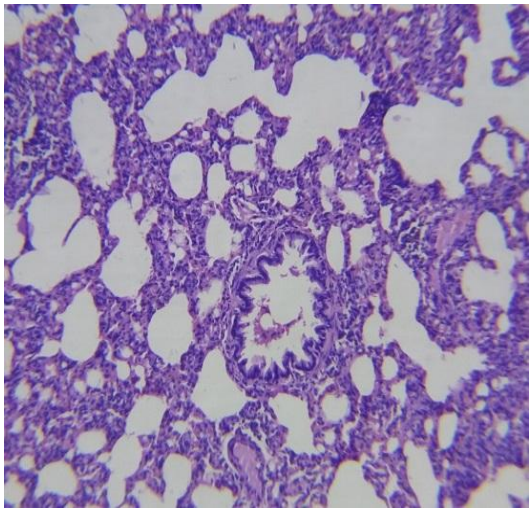


High Power Magnification 40X

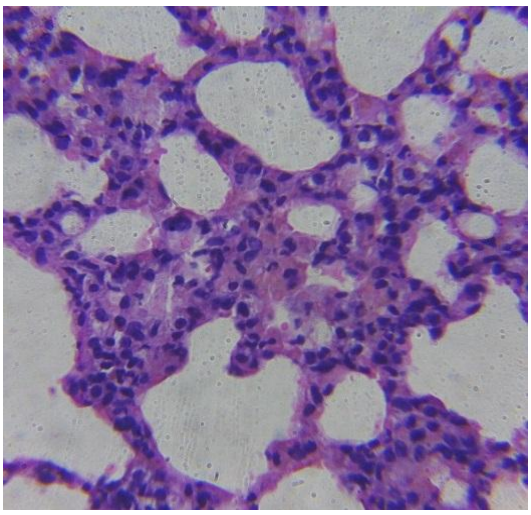


Histopathology of Lung

Low Power Magnification 10X

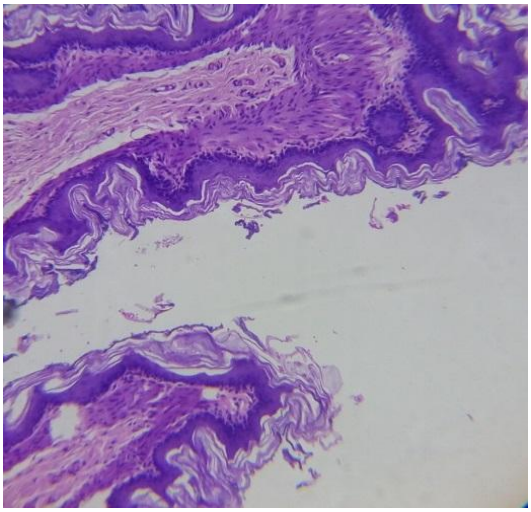


High Power Magnification 40X

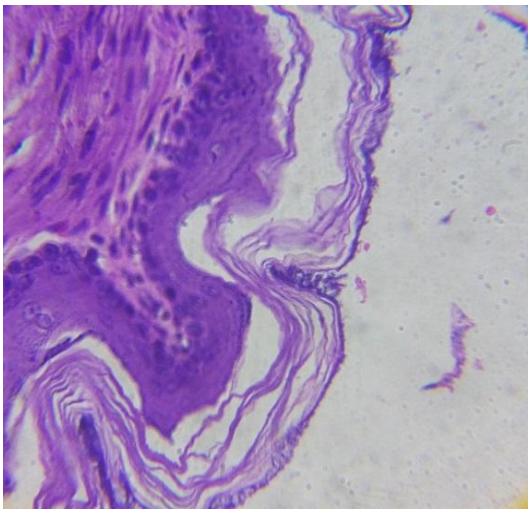


Histopathology of Stomach

Low Power Magnification 10X

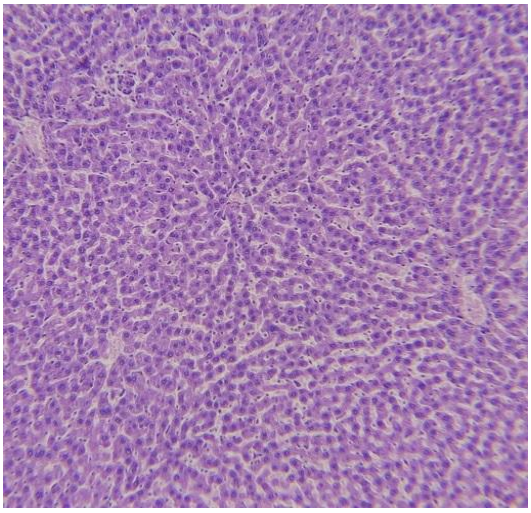


High Power Magnification 40X

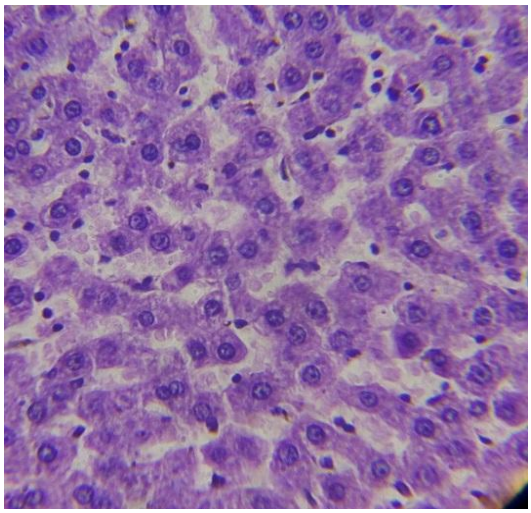


Histopathology of Liver

Low Power Magnification 10X

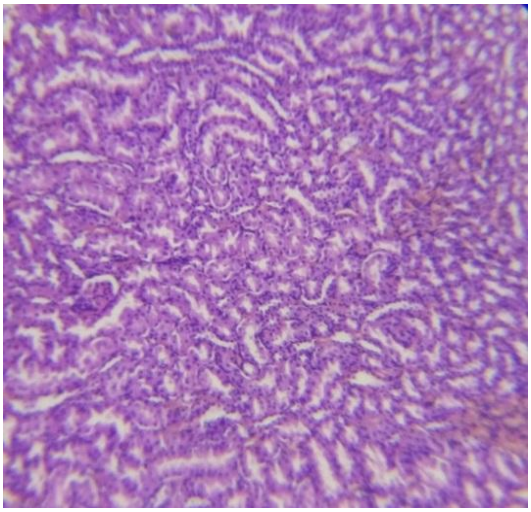


High Power Magnification 40X

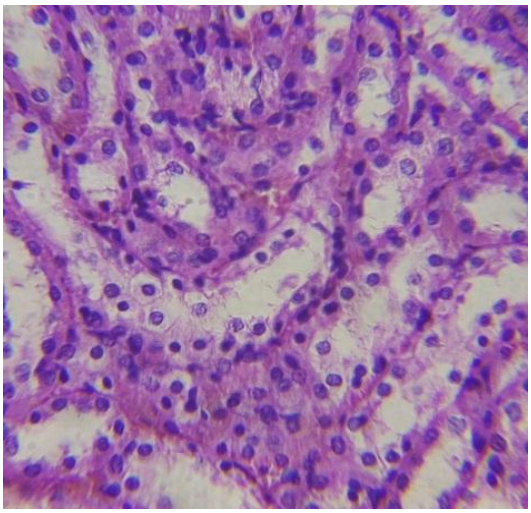


Histopathology of Kidney

Low Power Magnification 10X

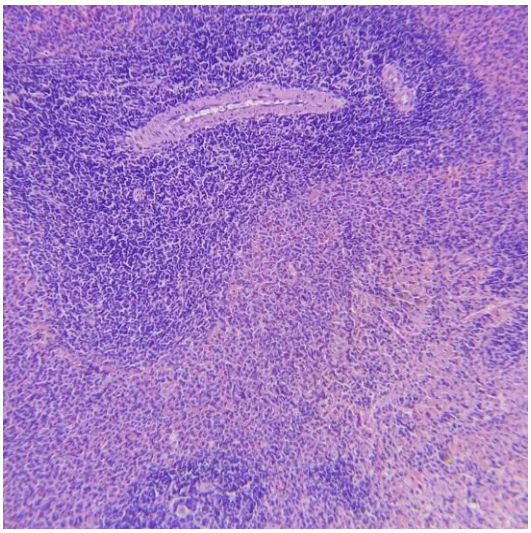


High Power Magnification 40X

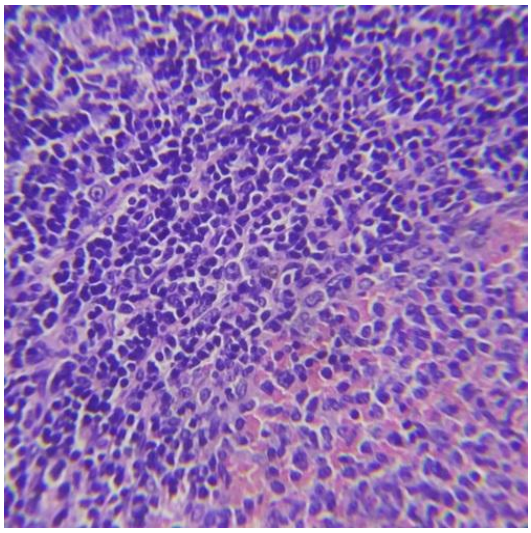


Histopathology of Spleen

Low Power Magnification 10X

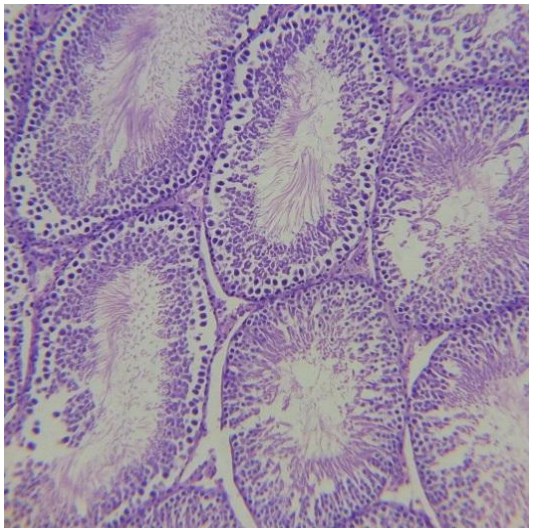


High Power Magnification 40X

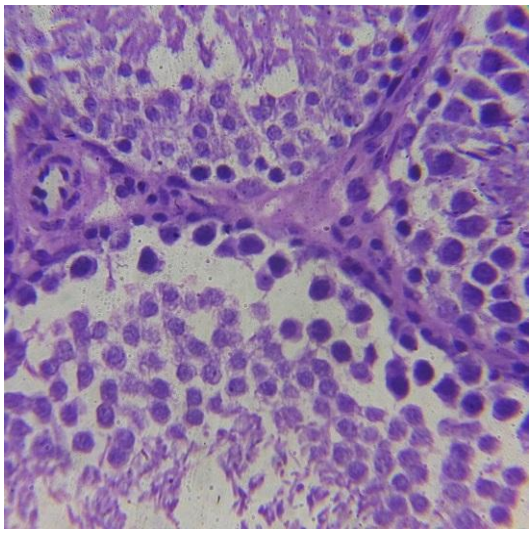


Histopathology of Testes

Low Power Magnification 10X



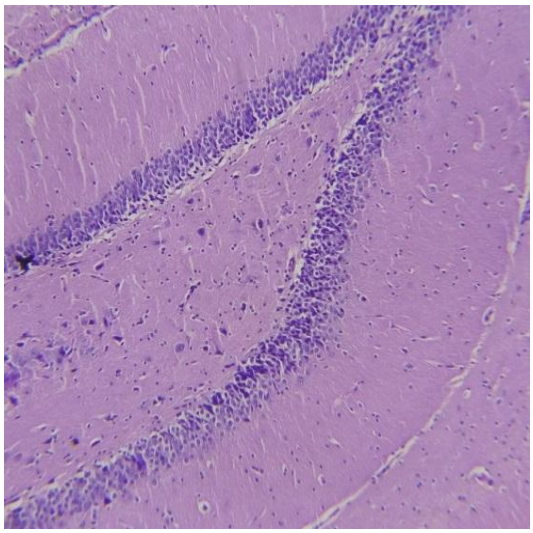
High Power Magnification 40X



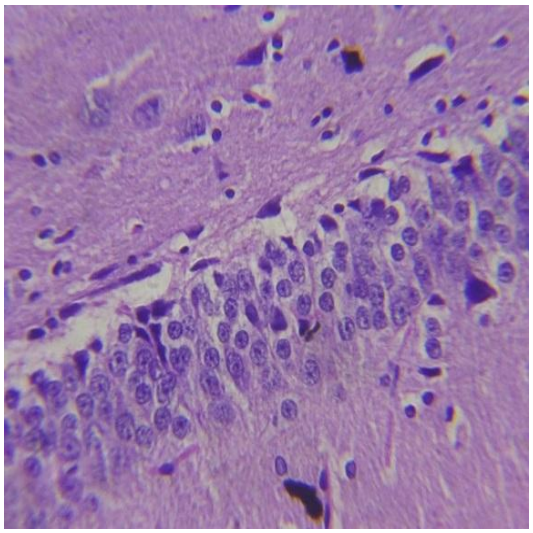
HIGH DOSE – FEMALE

Histopathology of Brain

Low Power Magnification 10X

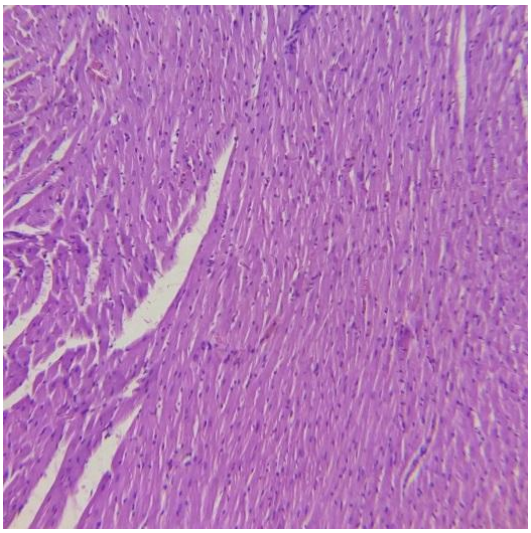


High Power Magnification 40X

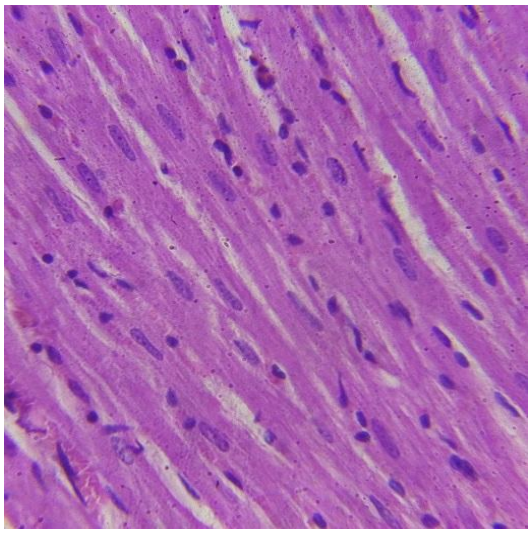


Histopathology of Heart

Low Power Magnification 10X

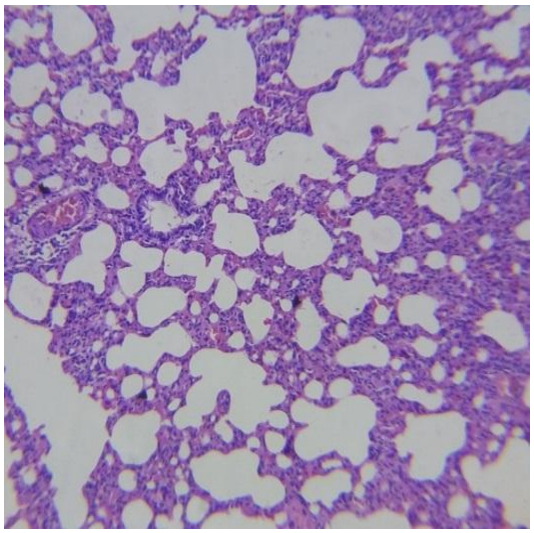


High Power Magnification 40X

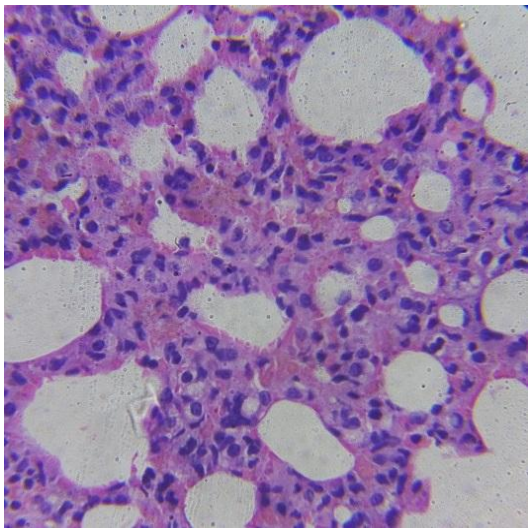


Histopathology of Lung

Low Power Magnification 10X

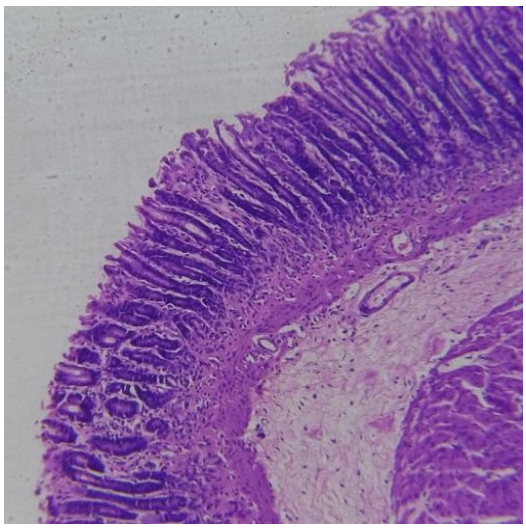


High Power Magnification 40X



Histopathology of Stomach

Low Power Magnification 10X



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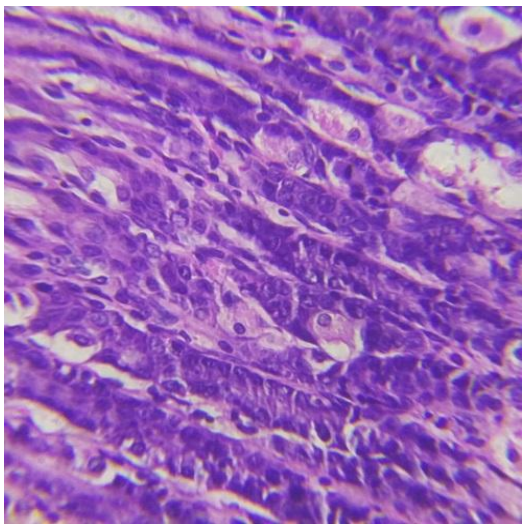
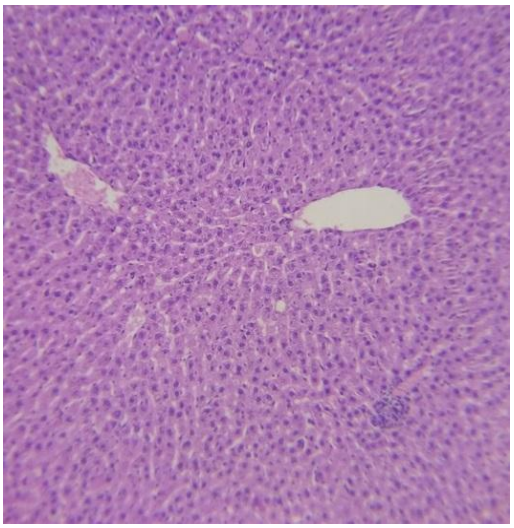


Histopathology of Liver

Low Power Magnification 10X



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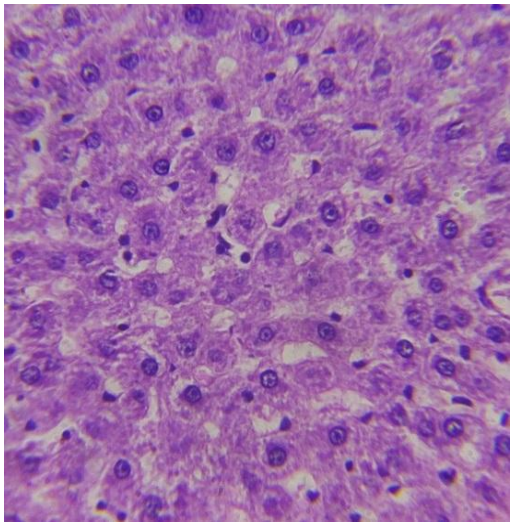
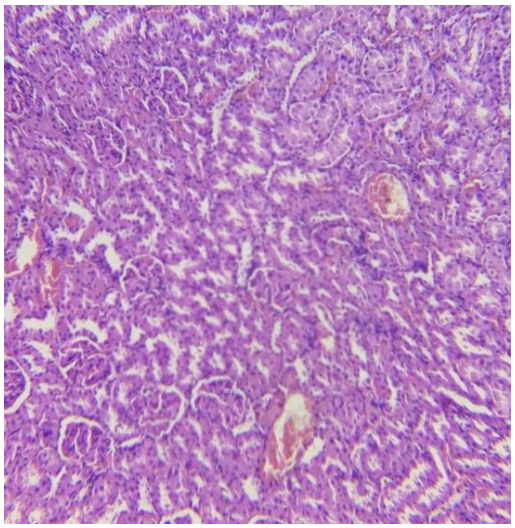


Histopathology of Kidney

Low Power Magnification 10X



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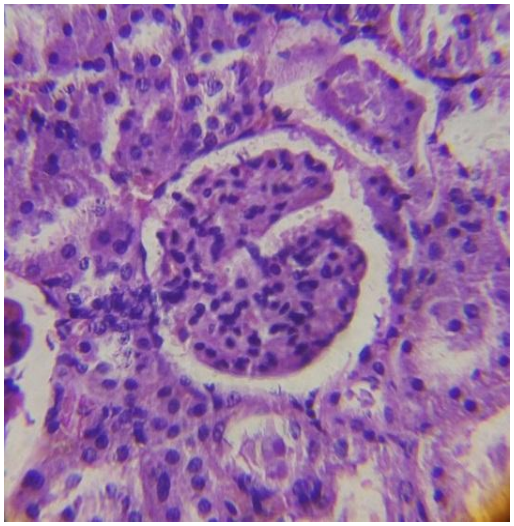
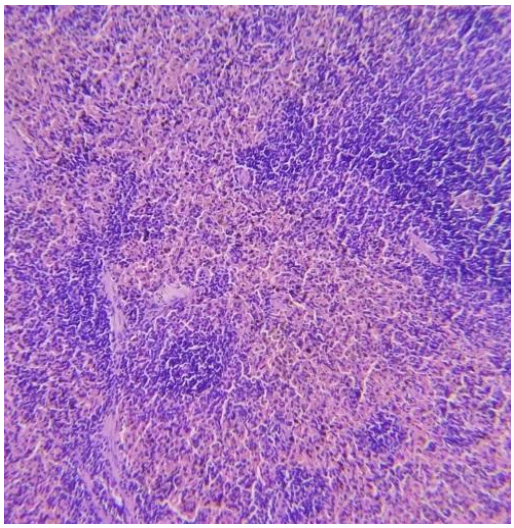


Histopathology of Spleen

Low Power Magnification 10X



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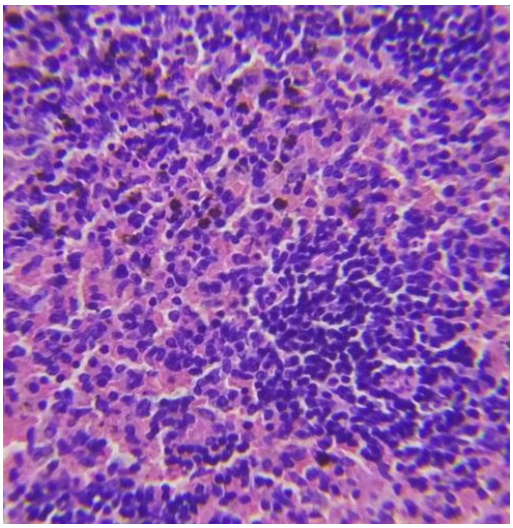
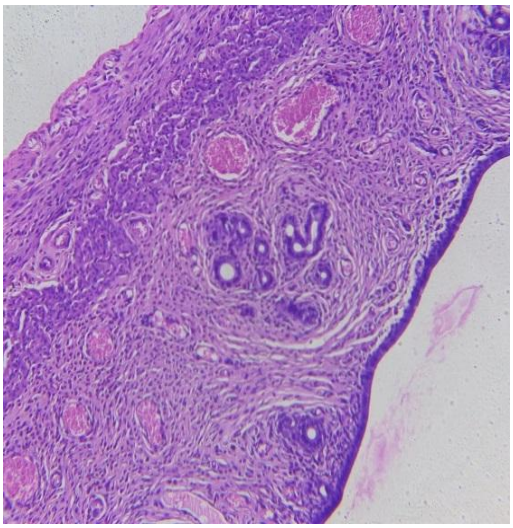


Histopathology of Uterus

Low Power Magnification 10X



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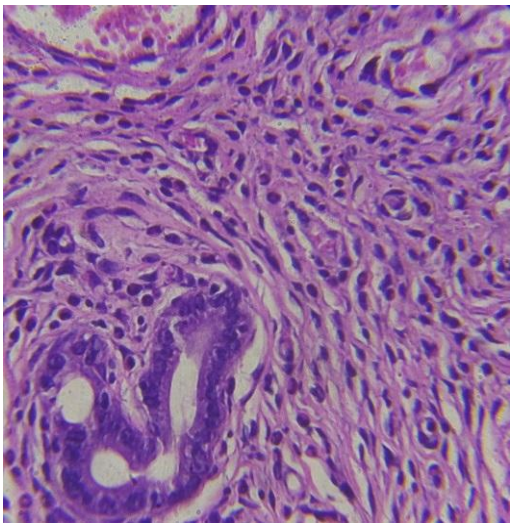
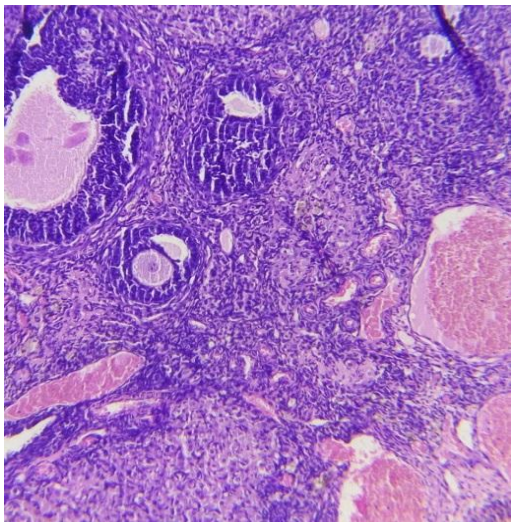


Histopathology of Ovary

Low Power Magnification 10X



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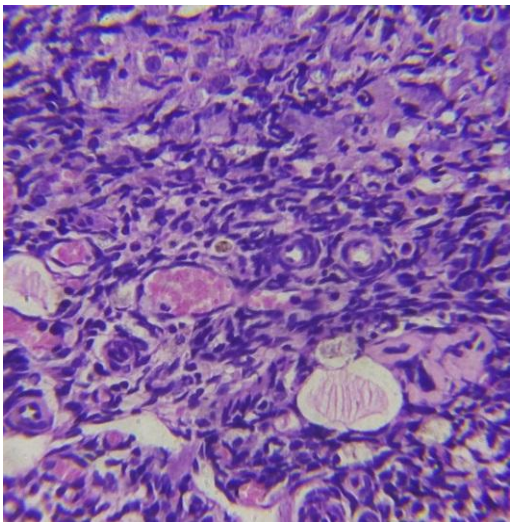


CLINICAL STUDY

95 subjects were screened for diabetes at National Institute of Siddha. Subjects those fulfilled the inclusion criteria were recruited after obtaining informed consent. Totally 44 numbers of individuals of both genders were recruited in this study. 4 patients had withdrawn from the study. 40 patients had completed the entire course of trial period.

Number of patients screened for eligibility: 95

Number of patients included in trial: 44

Number of patients withdrawn from the trial: 4

Number of patients who reported adverse drug reactions: 0

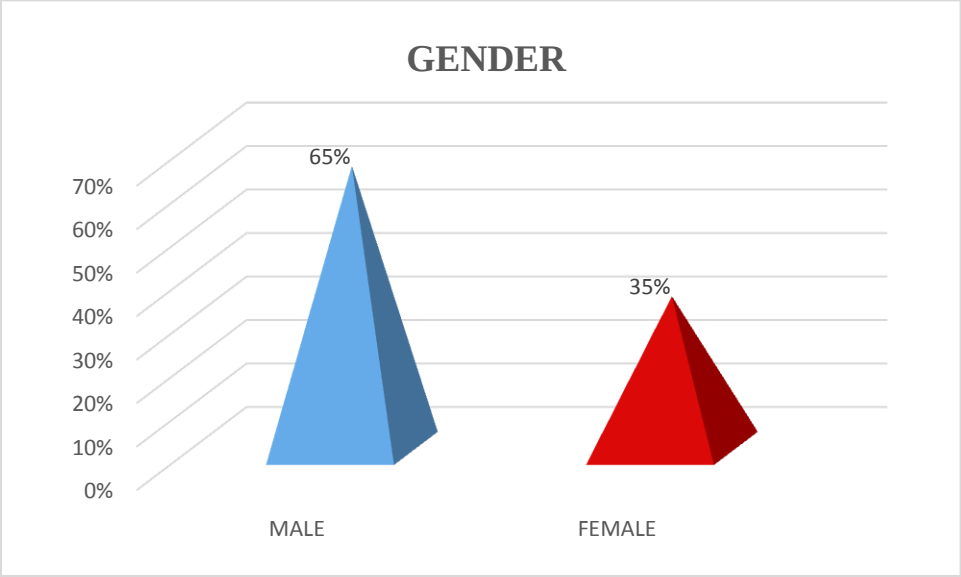
Duration of trial: 90 days (treatment period)

The observation and results were studied and tabulated under the following heading.

- Sex distribution
- Age distribution
- Religion
- Occupational status
- Socio economic status
- Family History
- Personal habits
- Dietary habits
- Thinai distribution
- Gunam distribution
- Kaalam distribution (According to Age)
- Paruva Kaalam
- UdarKattukkal reference
- Distributions of three thodams
- En Vagaithervugal
- Clinical features
- Chronicity of illness
- Result

GENDER DISTRIBUTION:

S.NO	SEX	NO.OF CASES	PERCENTAGE
1	Male	26	65%
2	Female	14	35%

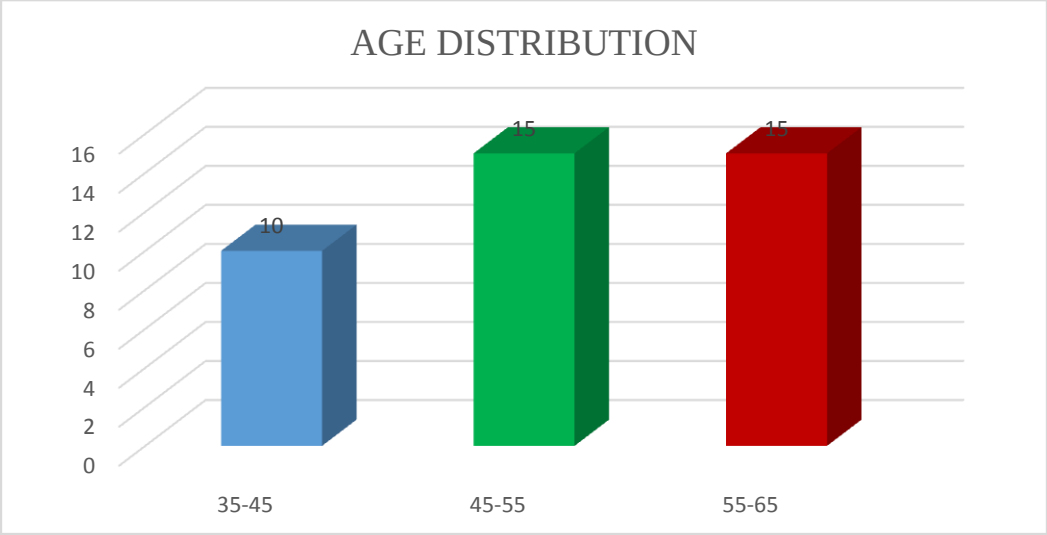


Observation:

Among the 40 patients selected for this study, 65% were males and 35% females.

DISTRIBUTION OF AGE INTERVAL:

S.NO	AGE INTERVAL	NO.OF CASES	PERCENTAGE
1	35-45	10	25%
2	45-55	15	37.5%
3	55-65	15	37.5%

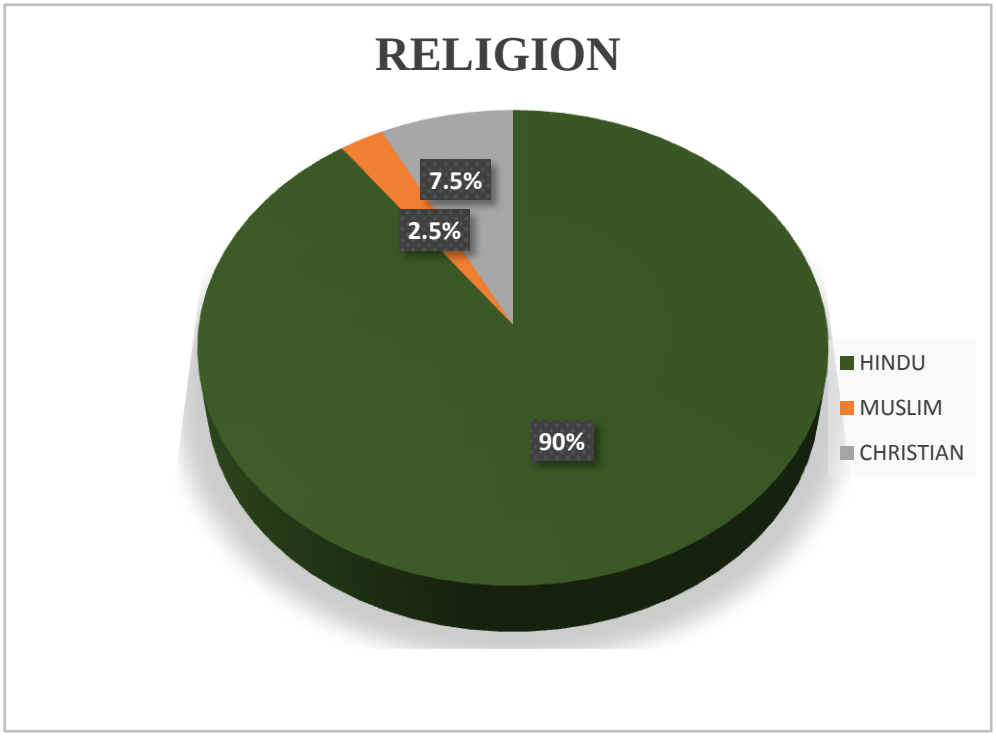


Observation:

Age group 35-45 were 25% (10cases), age group 45-55 were 37.5% (15 cases), and age group 55-65 were 37.5% (15 cases).

RELIGION:

S.NO	RELIGION	NO.OF CASES	PERCENTAGE
1	Hindu	36	90%
2	Muslim	1	2.5%
3	Christian	3	7.5%

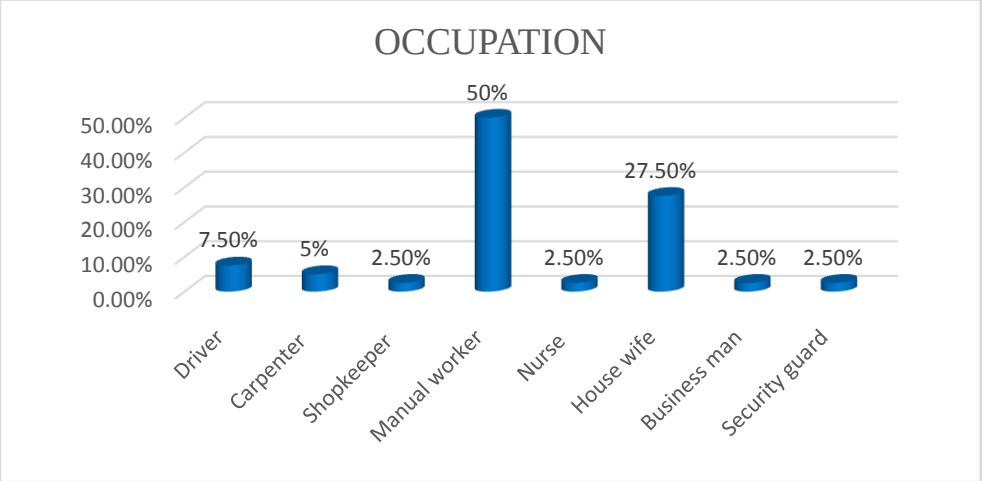


Observation:

Out of 40 cases 90% of patients (36) were Hindu, 2.5% (1) patients wasMuslim, and 7.5% of patients (3) were Christian**.**

OCCUPATIONAL STATUS:

S.NO	OCCUPATION	NO.OF CASES	PERCENTAGE
1	Driver	3	7.5%
2	Carpenter	2	5%
3	Shopkeeper	1	2.5%
4	Manual worker	20	50%
5	Nurse	1	2.5%
6	House wife	11	27.5%
7	Business man	1	2.5%
8	Security guard	1	2.5%

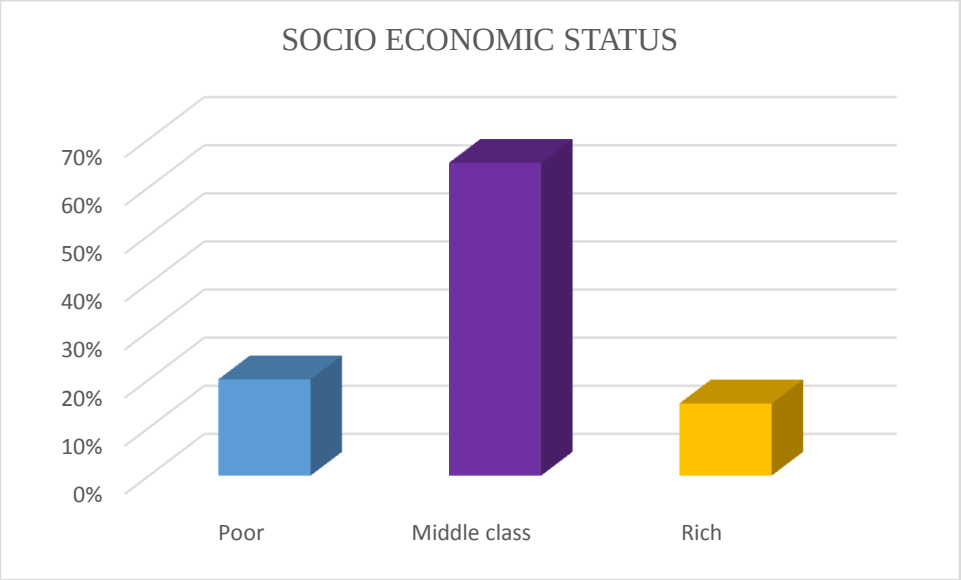


Observation:

Out of 40 cases 7.5% of patients (3) were Drivers, 5% (2) patients were Carpenter, 2.5% (1) case was shop keeper, 50% of patients (20) were manual workers, 27.5% of patients (11) were house wives, 2.5% (1) case was nurse, 2.5% (1) case was business man and 2.5% (1) case was security**.**

SOCIO ECONOMIC STATUS

S.NO	SOCIO ECONOMIC STATUS	NO.OF CASES	PERCENTAGE
1	Poor	8	20%
2	Middle	26	65%
3	Rich	6	15%

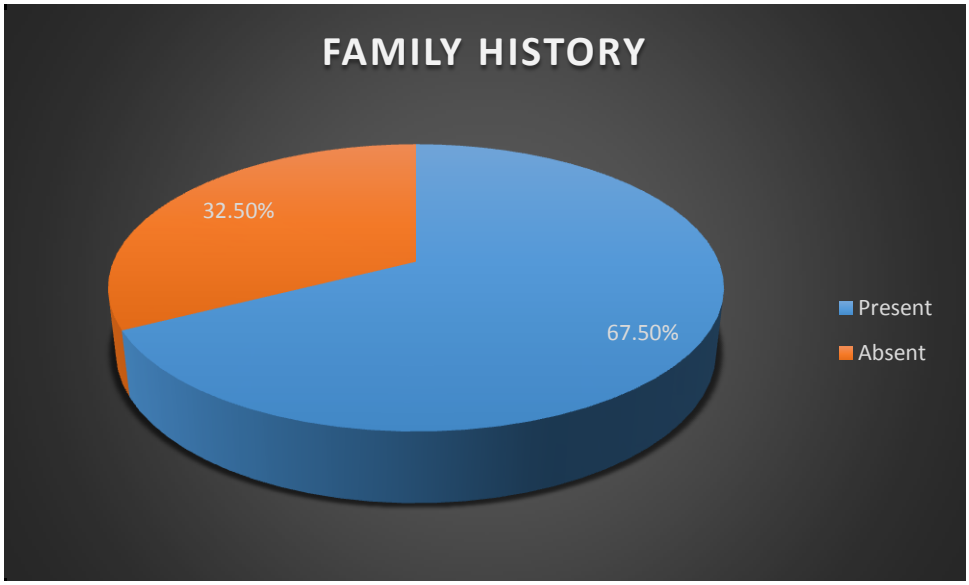


Observation:

Among 40 patients 20% of cases (8) were under poor socio- economic status and 65%of cases (26) were from middle class family and 15% of cases (6) were rich**.**

FAMILY HISTORY

S.NO	FAMILY HISTORY	NO.OF CASES	PERCENTAGE
1	Present	27	67.5%
2	Absent	13	32.5%



Observation:

Out of 40 Patients 27 cases (67.5%) had positive family history of type 2 diabetes, reveals genetic predisposition of the disease.

PERSONAL HABITS:

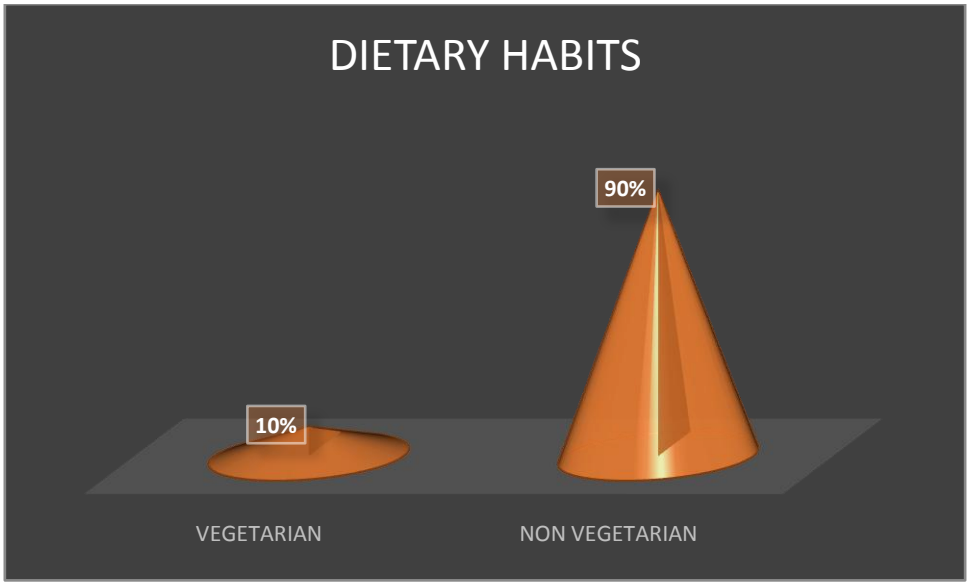
S.NO	PERSONAL HABITS	NO.OF CASES	PERCENTAGE
1	Smoker	9	22.5%
2	Alcoholic	11	27.5%
3	Non Smoker / Non Alcoholic	20	50%

Observation

Out of 40 cases 22.5% of patients (9) were smokers, 27.5 % (11) patients were alcoholic, and 50% (20) cases were Non-smokers & Non Alcoholic. Irrespective of personal habits the disease affects all groups such as smokers, alcoholic, non-smokers & non alcoholic

DIETARY HABITS

S.NO	DIET	NO.OF CASES	PERCENTAGE
1	Vegetarian	4	10%
2	Non vegetarian	36	90%

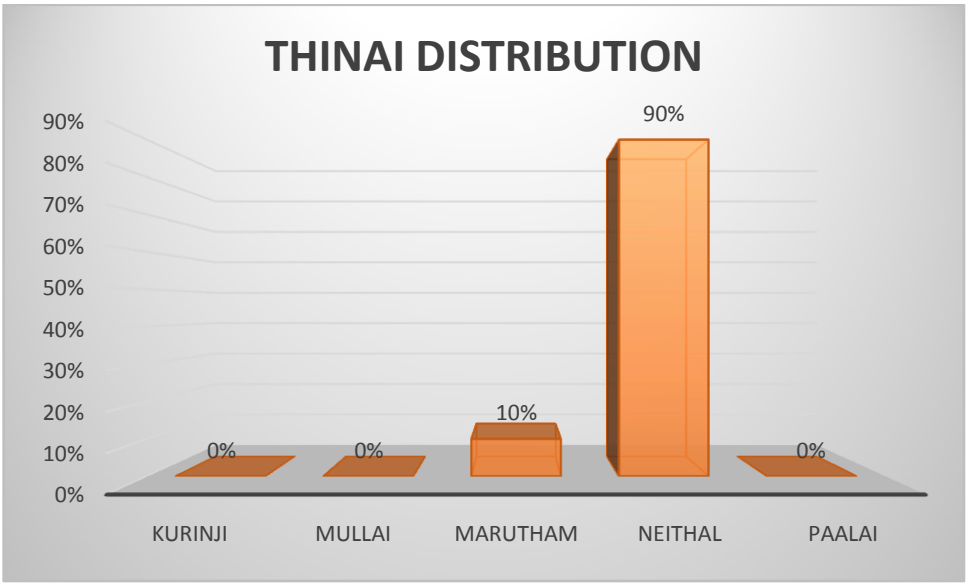


Observation:

Non vegetarian (90%) are more prone to*madhumegam* than vegetarians.

THINAI DISTRIBUTION:

S.NO	THINAI	NO.OF CASES	PERCENTAGE
1	Kurinji	-	-
2	Mullai	-	-
3	Marutham	10	90%
4	Neithal	36	10%
5	Paalai	-	-

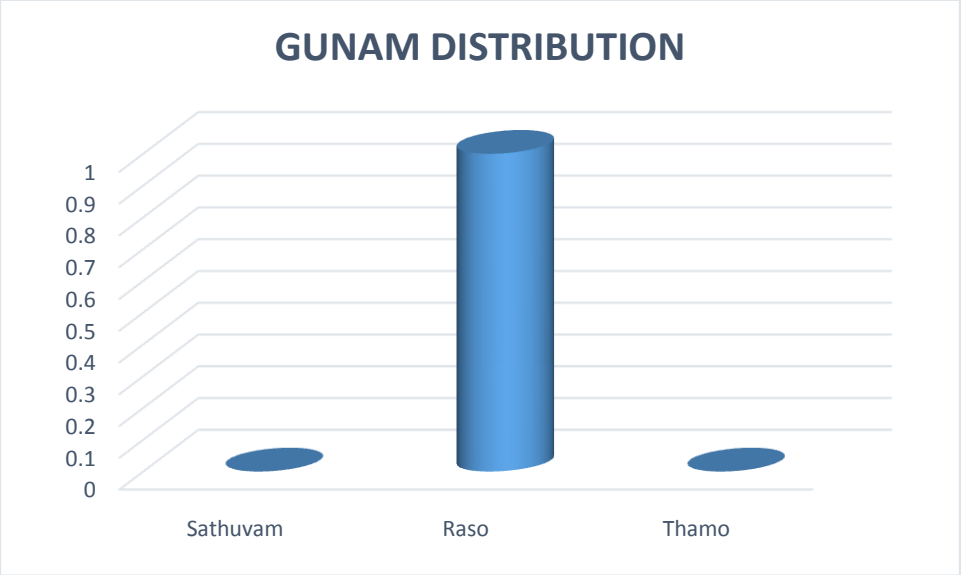


Observation:

Out of 40 cases 10% of patients (4 cases) were from *Marutham thinai* and 90% (36 cases) were from *Neithal thinai*.

GUNAM:

S.NO	GUNAM	NO.OF CASES	PERCENTAGE
1	Sathuvam	0	0
2	Raso	40	100%
3	Thamo	0	0

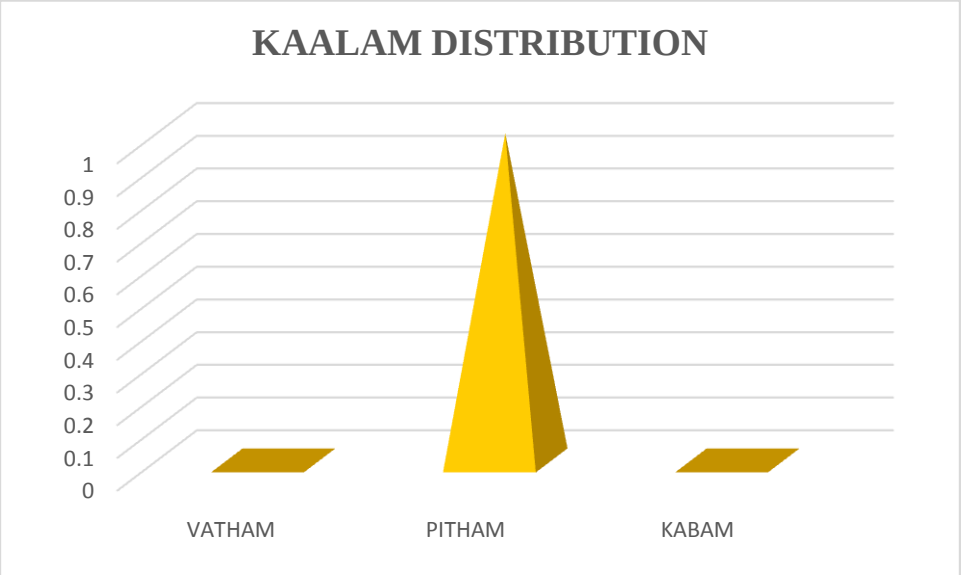


Observation:

Out of 40 cases all patients had *raso gunam*.

KAALAM DISTRIBUTION:

S.NO	KAALAM	NO.OF CASES	PERCENTAGE
1	Vatham(1-33 years)	0	0
2	Pitham(34-66 years)	40	100%
3	Kabam(67-99 years)	0	0

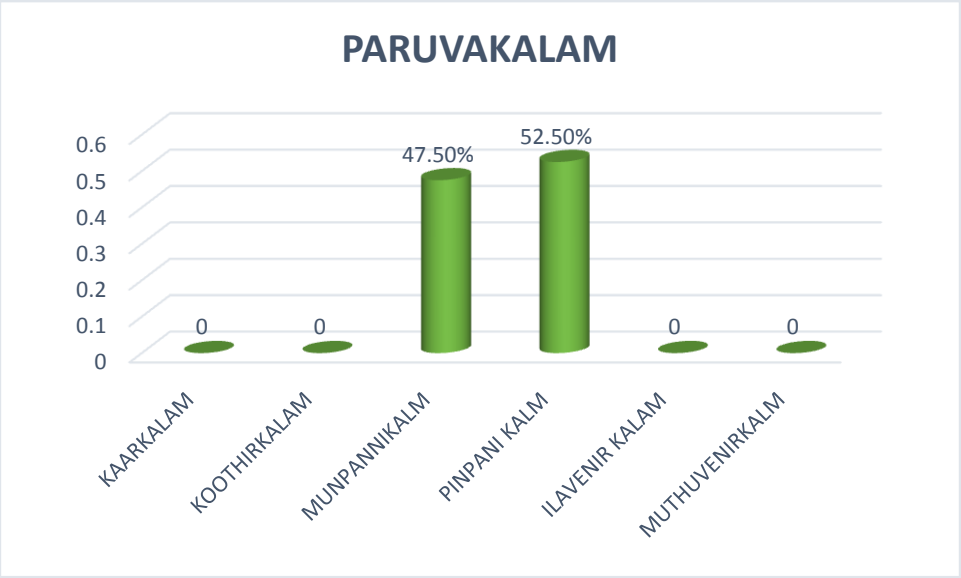


Observation:

All the patients included for the study were from *pitha kalam* (34-66 years)

PARUVA KAALAM:

S.NO	PARUVA KAALAM	NO.OF CASES	PERCENTAGE
1	Kar kaalam	0	0
2	Koothir kaalam	0	0
3	Munpani kaalam	19	47.5%
4	Pinpani kaalam	21	52.5%
5	Ilavenir kaalam	0	0
6	Muthuvenir kaalam	0	0

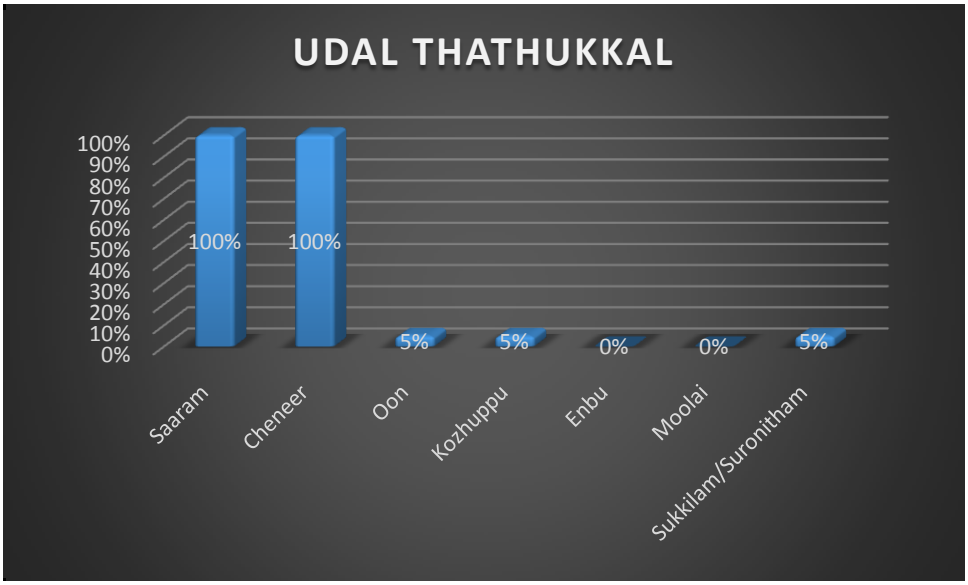


Observation:

Out of 40 cases 47.5% of patients (19 cases) were included in *Munpanikalam*, 52.5% (21cases) patients were in *Pinpani kalam.*

UDAL THATHUKKAL:

S.NO	UDAL THATHUKKAL	NO.OF CASES	PERCENTAGE
1	Saram	40	100%
2	Cheneer	40	100%
3	Oon	2	5%
4	Kozhuppu	2	5%
5	Enbu	0	0
6	Moolai	0	0
7	Sukkilam	2	5%



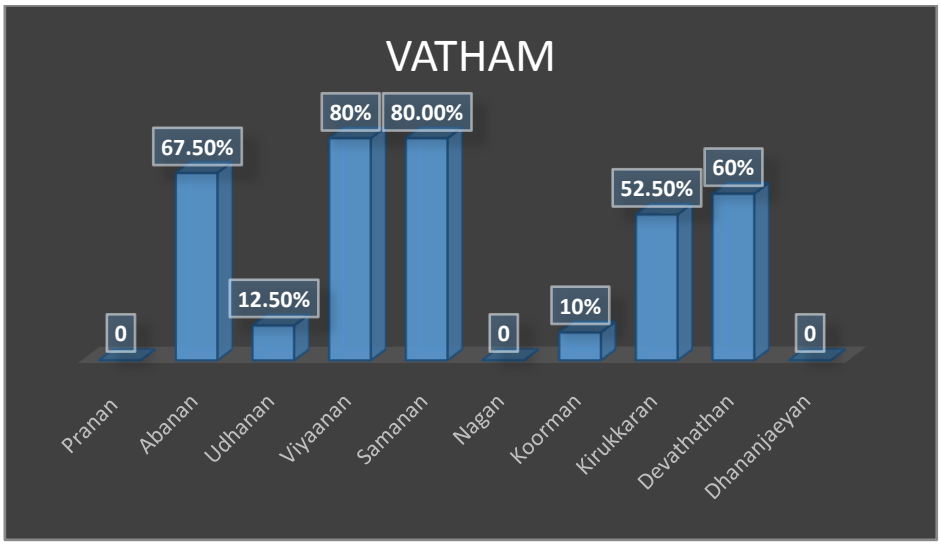
Observation:

*Udal Thathukkal Saaram&Chenneer*wasaffected in all cases. *Oon* and *Kozhuppu* was affected in 5% (2 cases) each. *Sukilam* was affected in 5% (2 cases).

MUKKUTRANGAL:

VATHAM:

S.NO	VATHAM	NO.OF CASES	PERCENTAGE
1	Pranan	0	0%
2	Abanan	27	67.50%
3	Udhanan	5	12.5%
4	Viyanan	34	85%
5	Samanan	34	87.50%
6	Nagan	0	0
7	Koorman	4	10%
8	Kirukaran	4	10%
9	Devathathan	24	60%
10	Dhananjeyan	0	0

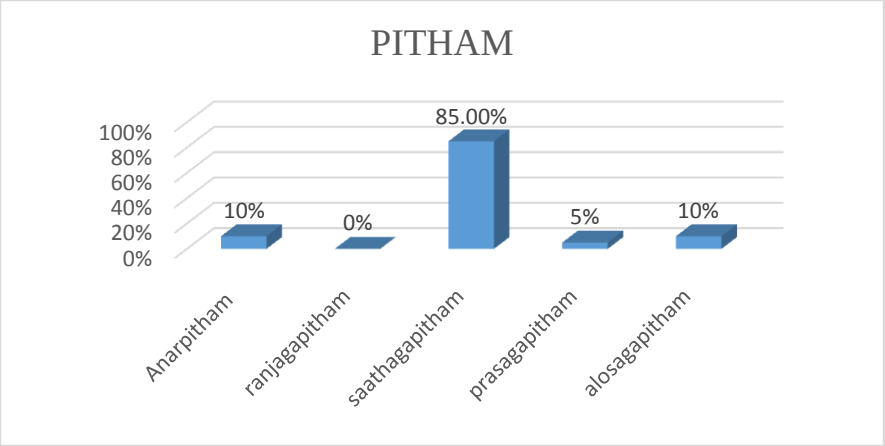


Observation:

Viyaanan (pain present in the both upper and lower limbs, burning sensation presentin the both soles) was affected in 85% (34cases). *Udhanan* (tiredness, drowsiness) was affected in 12.5% (5 cases) and *Abaanan* (polyuria, constipation, nocturia)was affected in 67.5% (27 cases), *Samaanan* was affected 90%(36cases) and *Kirukaran* (polyphagia)was affected in 10% (4cases), *koorman* was affected in (10% (4cases), and *Devathaththa*n (tiredness,anxiety) was affected in 60% (24 cases).

PITHAM

S.NO	PITHAM	NO.OF CASES	PERCENTAGE
1	Anarpitham	4	10%
2	Ranjagapitham	0	0%
3	Saathagapitham	34	85%
4	Prasagam	2	5%
5	Alosagam	0	0%

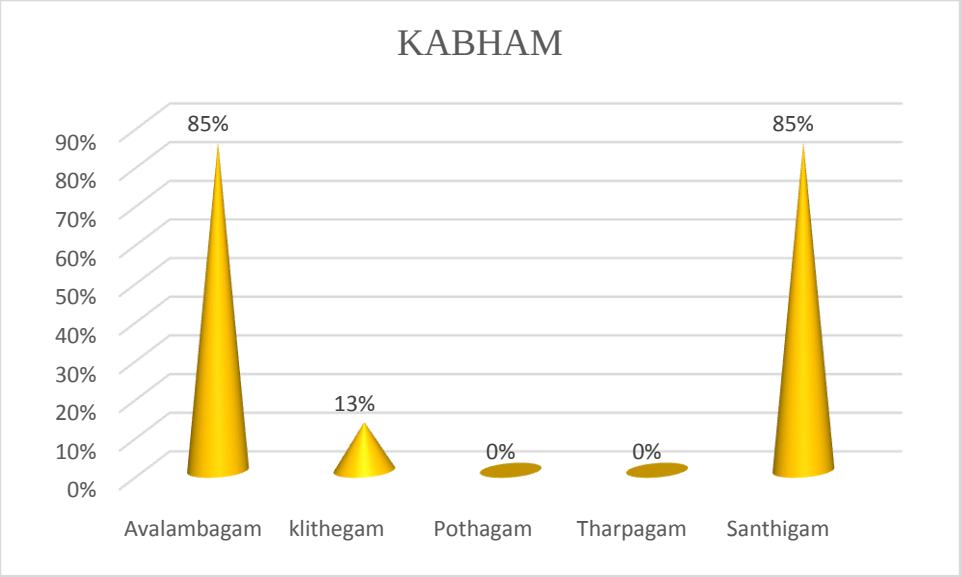


Observation:

Among 40 cases *Saathaga pittham* (general tiredness) was affected in 85% (34 cases). *Anal pittham* (Increased appetite) was affected in 10% (4 cases), *Pirasaga pittham* (Dryness of skin) was affected in 5% (2 cases),*Aalosaga pitham* (dullness of vision) was affected in 10% (4 cases).

KABAM:

S.NO	KABAM	NO.OF CASES	PERCENTAGE
1	Avalambagam	34	85%
2	Kilethagam	5	12.5 %
3	Pothagam	0	0
4	Tharbagam	0	0
5	Santhigam	34	85%

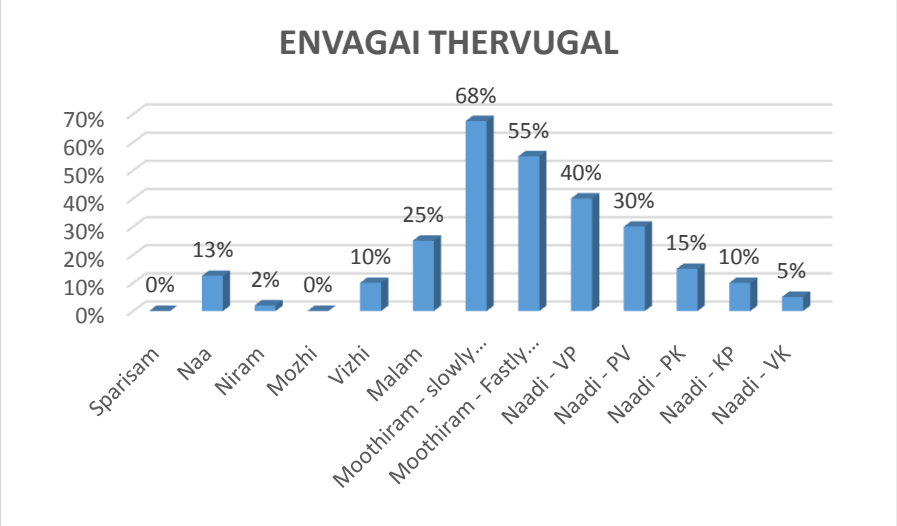


Observation:

Among 40 patients *Avalambagam* was affected in 85% (34cases), *Kilethagam*(increased appetite) was affected in 12.5% (5cases), *Santhigam*(Joint pain) was affected in 85% (34cases).

ENVAGAI THAERVUGAL:

S.NO	Envagai Thervu	NO.OFCASES	PERCENTAGE
1	Naa	4	10%
2	Niram	2	50%
3	Mozhi	0	0
4	Vizhi	4	10%
5	Malam	0	0
6	Moothiram		
	Slowly spread	27	67.5%
	Fastly spread	22	55%
7	Naadi		
	Vatha pitham	16	40%
	Pitha vatham	12	30%
	Pitha kabham	6	15%
	Kabha pitham	4	10%
	Vatha kabham	2	5%
8	Sparisam	0	0

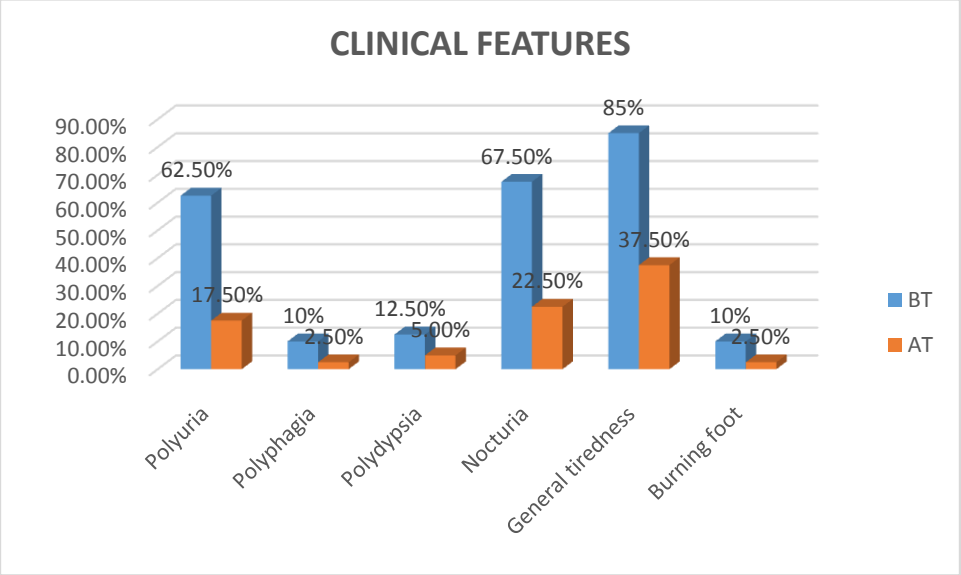


Observation:

In *Ennvagai thervugal* oil in urine (*Neikuri*) was slowly spread in 67.5% (27cases). fastly spread in 55% (22cases). *Vizhi* (Eye) affected (burning sensation of both eyes/cataract/diminished vision) in 10% (4 cases) and *Naa* was affected in 10% (4 cases). *Naadi* was *vaatha piththam* in 40%(16) cases, *Piththa vaatham* in 30% (12) of cases and *Piththa kapham* in 15% (6) of cases and *vatha kapham* in 5%(2) of cases, *Kapha pitham* was noted in 10% (4) cases.

CLINICAL FEATURES:

CLINICAL FEATURES	NO.OF CASES		IMPROVEMENT%	
	BEFORE TREATMENT	AFTER TREATMENT	BEFORE TREATMENT	AFTER TREATMENT
Polyuria	25	7	62.5%	17.5%
Polyphagia	4	1	10%	2.5%
Polydipsia	5	2	12.5%	5%
Nocturia	27	9	67.55%	22.5%
General tiredness	34	15	85%	37.5%
Burning foot	4	1	10%	2.5%

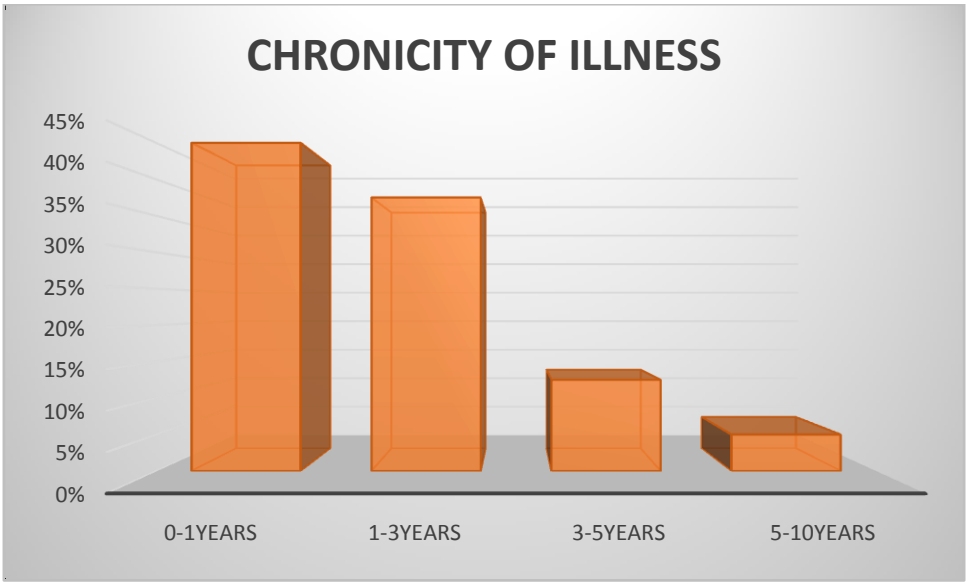


Observation:

62.50% (25cases) had complains of polyuria and 10 % (4 cases) had complaints of Polydipsia 12.5 % (5 cases) had complaints of polyphagia, 67.5 % (27 cases) had complaints of nocturia, ,10%(4cases) had complaints of pain and burning sensation in the both sole, and 85% (34 cases) had complaints of Tiredness.

CHRONICITY OF ILLNESS:

S.NO	CHRONICITY OF ILLNESS	NO.OF CASES	PERCENTAGE
1	0-1 years	18	45%
2	1-3 years	15	37.5%
3	3-5 years	5	12.5%
4	5-10 years	2	5%



Observation:

45% (18 patients) had the history of this disease up to 0-1 years only. 37.5% (15 patients) suffered for1-3 years and 12.5 % (5patients) for3-5 years. And 5% (2 patients) for 5-10 years.

Statistical significance of biochemical values in *Maruthampattai Kudineer* treated patients

FASTING BLOOD SUGAR

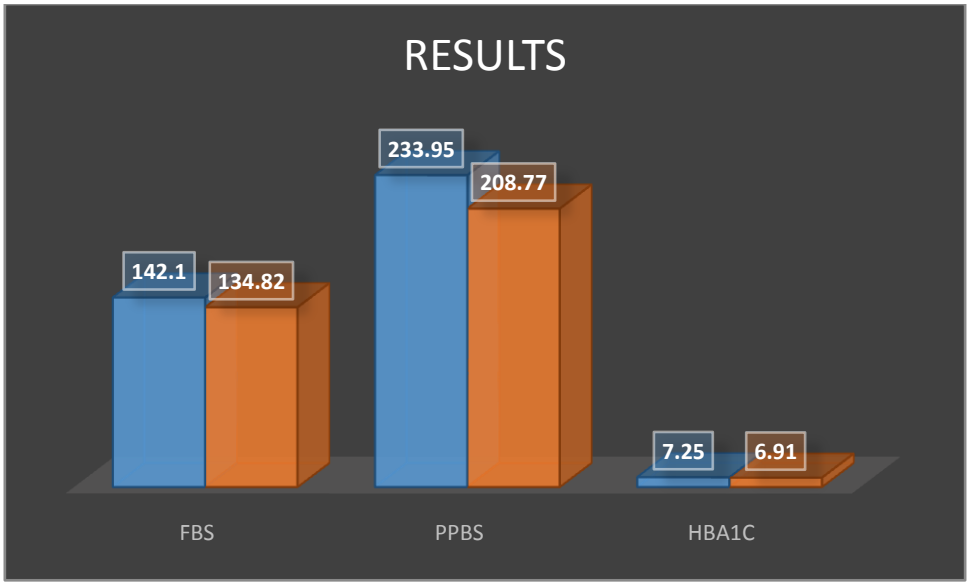
	No .of patients	**Mean ±SD**	**P value**	**T value**
Before treatment	40	142.1± 33.08	0.34	2.193
After treatment	40	134±26.49		

POSTPRANDIAL BLOOD SUGAR

	No .of patients	**Mean ±SD**	**P value**	**T value**
Before treatment	40	233.95± 50.79	0.0007	3.68
After treatment	40	208.77 ±53.60		

GLYCOSYLATED HAEMOGLOBIN

	No .of patients	**Mean ±SD**	**P value**	**T value**
Before treatment	40	7.25 ± 0.91	0.0025	3.225
After treatment	40	6.91 ±0.86		



GROUP	NO.OF PATIENTS	GOOD CONTROL	POOR CONTROL
Group 1 (Trial medicine with yogam)	20	15	5
Group 2 (Only trial medicine)	20	9	11

Observation:

The outcome of the study showed encouraging results.Hba_1c which is a reliable biomarker for the diagnosis and prognosis of diabetes was found to be under good control in 15 patients and poor control in 5 patient in group 1 patients treated with trial medicine and yogam.It was found to in good control in 9 patients and poor control in 11 patients in group 2 treated with the trial medicine alone.

DISCUSSION

Diabetes is a metabolic disorder with an alarming rise in its incidence.It affects the quality of life of a person. The goal of diabetes management is to prevent or treat the many complications that can result from the disease itself and from its treatment.

The trial drug was prepared in Gunapadam lab of National Institute of Siddha after the authentication of the raw drugs by Assistant professor of medicinal botany NIS Chennai.

The Bio chemical analysis was done at the biochemistry lab of NIS and the results were documented. The Bio-chemical analysis of *Kukkil chooranam* had shown the presence of **Sulphate, Phosphate, Carbonate, Calcium,Alkaloids, Tannic acid, Oxyquinalone,epinephrine and pyro catechol.Their presence indicates the antioxidant, antimicrobial, anti-septic, properties of the drug.**

The physico chemical analysis demonstrated the following results with pH (10 % w/v aq. solution**4.96,** Loss on drying at 105°C**11.58 %,**Total ash value **16.74 %,** Acid-insoluble ash value **0.98 %,**Water-soluble extractive**24.29 %,**Alcohol soluble extractive**18.96 %.**

The α –amylase anti diabetic activity revealed high performance activity compared to the standard drug acarbose. The trial drug exhibited comparable antioxidant property done using ABTS assay.

The Acute and 90 days repeated oral toxicity studies did not show any toxic effects in the animals.

Clinical study:

For this study, 40 patients were selected and patients were treated in the OP department of Sirappu Maruthuvam, in Ayothidoss Pandithar Hospital of National Institute of Siddha, Tambaram Sanatorium, Chennai – 600 047.

The trial drug maruthampattai kudineer was given for 90 days. OPD patients were requested to visit the hospital once in 7 days. In each and every visit clinical assessment and prognosis were recorded. Group II patients were taught Yogasanam on each visit. Laboratory investigations were done for all the cases before and after treatment. Based on various criteria, the data were collected and tabulated. The criteria were family history, sex predominance, age distribution, occupation, dietary habits, chronicity of illness and clinical features assessment of the improvement in the prognosis of the disease with the trial drug.
40 patients of both genders were recruited for this study. Among the 40 cases, 26 (65%) were males and 14 (35%) were females. Generally diabetes occurs with high incidence in male compared to female. More number of male cases reported in this study.

Among 40 patients admitted in the trial 25% (10cases) were in the age group of 35-45 , 37.5% (15 cases) were in the age group 45-55 and 37.5% (15 cases) were in the age group 55-65.

Out of 40 cases 90% of patients (36 cases) were Hindu.

Out of 40 cases 7.5% of patients (3) were Drivers, 5% (2) patients were Carpenter, 2.5% (1) case was shop keeper, 50% of patients (20) were manual workers, 27.5% of patients (11) were house wives, 2.5% (1) case was nurse, 2.5% (1) case was business man and 2.5% (1) case was security.

Out of 40 Patients 27 cases (67.5%) had positive family history of Type 2 diabetes reveals genetic predisposition of the disease.

Out of 40 cases 22.5% of patients (9 cases) were smokers, 27.5% (11) patients were alcoholic, and 50 % (20) cases were Non-smokers& Non Alcoholic. Irrespective of personal habits the disease affects all groups such as smokers, alcoholic, non-smokers & non-alcoholic

The majority of patients in this study were Non vegetarian 36 (90%) remaining 4 (10%) patients were vegetarian.

In this present study, considerable numbers of patients reported from Neithal thinai (36 patients),Marutham thinai (4 patients).

All the patients included for the study were from pitha kalam (34-66 years) reveals the incidence of diabetes is commom among middle aged and old aged people.

Out of 40 cases all patients had raso gunam.

Among 40 cases most of them (21cases) were included in the trial in pinpanikalam,(52.5%) .

In Udal Thathukkal Saaram & Chenneer wasaffected in all cases. Oon and Kozhuppu was affected in 5% (2) of cases each. Sukilam was affected in 5% (2) of cases.

Viyaanan (pain present in the both upper and lower limbs, burning sensation presentin the both soles) was affected in 85% cases (34). Udhanan (tiredness, drowsiness) was affected in 12.5% (5 cases) and Abaanan (polyuria, constipation, nocturia)was affected in 67.5% (27 cases), Samaanan was affected 90%(36cases) and Kirukaran (polyphagia)was affected in 10% (4cases), koorman was affected in (10% (4cases), and and Devathaththan (tiredness,anxiety) was affected in 60% cases(24 cases).

Among 40 cases Saathaga pittham (general tiredness) was affected in 85% (34) cases. Anal pittham (Increased appetite) was affected in 10% of cases (4 cases), Pirasaga pittham (Dryness of skin) was affected in 5% cases (2cases), Aalosaga pitham (dullness of vision) was affected in 10% of cases (4).

Among 40 patients Avalambagam was affected in 85% (34cases), kilethagam(increased appetite) was affected in 12.5% (5cases), Santhigam(Joint pain) was affected in 37.5 %(15).

45% (18) patients had the history of this disease up to 0-1 years only. 37.5% (15) of patients suffered for1-3 years and 12.5 % (5) patients for3-5 years, and 5% (2) patients for 5-10 years.

In Ennvagai thervugal oil in urine (Neikuri) was slowly spread in 67.5% (27cases). fastly spread in 55% (22) cases. Vizhi (Eye) affected (burning sensation of both eyes/cataract/diminished vision) in 10% (4 cases) and Naa was affected in 10% (4 cases). Naadi was vaatha piththam in 40%(16) cases, Piththa vaatham in 30% (12) of cases and Piththa kapham in 15% (6) of cases and vatha kapham in 5%(2) of cases, Kapha pitham was noted in 10% (4) cases.

62.50% (25cases) patients had complains of polyuria and 10 % (4 cases) complaints of Polydipsia 12.5 % (5 cases) complaints of polyphagia, 67.5 % (27 cases) complaints of nocturia, ,10%(4cases) complaints of pain and burning sensation in the both sole, and 85% (34 cases) complaints of Tiredness.the statistical significance of the biochemical parameters in maruthampattai kudineer treated subjects were expressed as Mean ± Standard Error of Mean . A probability value of <0.05 was considered to be statistically significant.

The mean± standard error of mean of fasting blood sugar before and after treatment were 142.1± 33.08 and 134.82± 26.49 respectively which is statistically significant (t = 2.1938, p value 0.0343)

The mean± standard error of mean of postprandial blood sugar before and after treatment were 233.95± 50.79 and 208.77± 53.60 respectively which is statistically significant (t = 3.6817, p value 0.0007)

The mean± standard error of mean of HBA_1C before and after treatment were 7.25± 0.918 and 6.91± 0.869 respectively which is statistically significant (t = 3.2257, p value 0.0025)

The outcome of the study showed encouraging results.Hba_1c which is a reliable biomarker for the diagnosis and prognosis of diabetes was found to be under good control in 15 patients and poor control in 5 patient in group 1 patients treated with trial medicine and yogam.It was found to in good control in 9 patients and poor control in 11 patients in group 2 treated with the trial medicine alone.

In this study, no adverse events were observed during the course of the treatment. At the end of the study, all the patients were advised to attend out-patient department of Sirappu Maruthuvam of NIS for further follow-up.

SUMMARY

This study protocol has been approved by Institutional Ethical Committee ofNIS (IEC Approval number: NIS/IEC/2016 11-09/14.10.2016)

The raw drugs of *Maruthampattai kudineer* were identified and authentication certificate was obtained.

The Biochemical analysis of the trial drug was done in the Biochemistry lab of National Institute of Siddha.

The physicochemical analysis of the prepared drug revealed that it was in the standard quality.

The toxicity study (acute and repeated-dose 90days toxicity) of the trial drug was done in NIS Chennai. The study shows that *Maruthampattai kudineer* did not produce any toxic effect at dose of 2000 mg/kg. So No-Observed-Adverse-Effect-Level (NOAEL) of *maruthampattai kudineer* is 2000 mg/kg.

The disease Madhumegam was taken for the clinical study with *Maruthampattai kudineer* and 40 cases were selected based on the approved protocol. Animal studies were done after obtaining approval from the Animal Ethical Committee (IAEC). Hence the study was safely executed on patients and there was no adverse drug reactions noted during the study period.All the patients were treated with Trial drug ***Maruthampattai kudineer*** before food twice a day for 90 days .Among the 40 patients 20 patients were adviced to do specific yoga module.

Haematological, Biochemical and Urine examination were done before and after treatment. Blood sugar (F) and (PP), HBA1c were done before and after treatment. Statistical Analysisweredone after treatment.

Because of the hopeful results clinically, the study may be undertaken with the samedrug for a prolonged period in more number of cases and it may throw new lights in the managemet of Madhumegam.

CONCLUSION

The poly herbal formulation *Maruthampattai kudineer* exhibited no toxicity on long term administration.

The present clinical study confirms the efficacy and safety of the trial drug "*Maruthampattai kudineer*" which is Siddha poly herbal formulation. It was found to be good resulting on madhumegam patients in maintaing their fasting, postprandial and HBA_1C levelsThe clinical symptoms such as polyuria, polydipsia, nocturia, and burning foot reduced considerably.

Though there are several classes of modern drugs available in the management diabetes they have their own characteristic profile of side effects.this present study highlights the point that the use of only a polyherbal medicine maruthampattai kudineer in management of diabetes was found to be efficacious. The intervention of yoga along with trial medicine produced better results. The present study enumerates the need to sensitize the community to adopt siddha medicines and yogam as a measure to manage diabetes.

S.NO	OP NO.	AGE/SEX	Hb		TC		DC										ESR				T.RBC	
							P		L		E		M		B		B.TMT		A.TMT			
			B.TMT	A.TMT	B.TMT	A.TMT	B.TMT	A.TMT	B.TMT	A.TMT	B.TMT	A.TMT	B.TMT	A.TMT	B.TMT	A.TMT	1/2 hr	1 hr	1/2 hr	1 hr	B.TMT	A.TMT
1	K01268	40/M	15.1	15	6500	6500	70	65	27	30	2	2	1	2	0	1	2	6	3	10	5.3	5.4
2	K04833	63/M	14.5	13.5	7500	7200	60	62	33	34	4	3	2	1	1	0	10	20	6	16	4.9	5
3	K10295	44/M	15.1	13.6	6100	5500	49	50	45	40	4	4	2	4	0	2	4	10	4	12	5.9	5.8
4	H40537	61/M	14.2	16	7100	7700	55	65	40	28	2	5	2	2	1	0	16	34	12	18	5.2	4.8
5	F83285	51/F	12	13.1	7500	7700	65	63	30	33	3	4	2	0	0	0	6	12	3	10	4.3	4.7
6	J64562	53/F	12.3	12	9600	9700	66	65	32	31	2	2	0	2	0	0	32	66	20	31	4.8	4.7
7	J63805	54/M	15	15	5800	5000	64	60	33	38	3	2	0	0	0	0	4	10	5	10	5.3	5.3
8	H62039	57/M	16.1	12.7	7400	8700	62	65	34	30	2	2	1	2	1	1	24	50	12	24	5.7	4.9
9	J48903	43/F	9.7	11.6	7500	7700	62	65	35	30	2	2	1	2	0	1	12	26	6	10	4.4	4.6
10	I29424	64/M	14.1	14.5	13400	9200	73	63	22	32	2	2	2	2	1	0	12	24	10	22	4.9	5.1
11	H09512	51/F	11	11.4	64	64	34	34	2	2	0	0	0	0	0	0	10	20	11	20	5	5.2
12	G94161	56/F	11.7	11.9	7700	8000	66	65	30	32	2	3	2	0	0	0	14	28	10	20	4.2	4.3
13	H7542	65/M	15	15	8600	8300	63	65	35	33	2	2	0	0	0	0	10	18	13	22	4.8	5
14	H08942	55/M	15.4	15.7	6000	6400	52	58	46	40	1	1	1	1	0	0	2	6	6	10	5.2	5.3
15	K03811	57/F	13.8	13.5	8800	8900	58	59	40	38	2	1	0	1	0	1	12	26	10	20	4.4	4.4
16	K08232	60/F	12.2	12.7	12300	11800	67	67	31	31	2	2	0	0	0	0	16	34	12	24	4.9	5.1
17	G14501	48/M	16	14.8	7800	7500	54	60	43	37	3	3	0	0	0	0	2	6	5	10	5.4	4.9
18	G90895	53/F	12	13.8	7500	8100	54	56	40	42	3	2	2	0	1	0	6	12	8	16	3.8	4.6
19	F93255	49/F	14	13.9	7900	8300	65	58	34	38	1	1	0	2	0	1	10	20	8	16	4.8	4.7
20	J90011	55/M	15	11.8	8100	8200	66	65	30	32	2	3	2	0	0	0	13	25	10	22	4.5	4.4
21	J74644	63/M	14.2	14	9300	9900	64	64	31	34	2	1	2	1	1	0	6	14	6	12	4.9	4.8
22	G88341	65/F	10.2	12	7700	7500	69	66	28	32	3	1	0	1	0	0	10	20	4	10	4.2	5
23	K02169	40/M	11	13.5	5200	6600	68	65	26	30	3	2	2	2	1	1	26	42	12	24	4.1	4.6
24	J73310	41/M	14.9	15.7	8100	10700	68	66	30	32	2	2	0	0	0	0	16	24	12	20	4.9	5.3
25	J39989	52/F	12.9	12.3	10000	9400	60	62	35	30	3	4	2	2	0	2	6	10	6	12	5.3	5.1
26	G81362	43/M	13.7	13.6	7500	8600	63	63	35	33	1	1	1	2	0	1	4	10	6	10	4.6	4.5
27	J69262	38/F	12.2	13.6	7500	7700	63	66	32	30	5	2	0	2	0	0	10	22	6	10	3.9	4.2
28	I1498	60/M	14.1	13.8	6200	5700	68	65	28	32	2	1	1	2	1	0	10	24	15	20	5.3	5.3
29	G95705	49/M	12	11.5	6800	4800	65	63	30	32	2	2	3	3	0	0	10	20	11	20	5.1	4.9
30	J54520	60/M	14	13.2	6200	7100	62	69	35	26	1	1	1	3	1	1	10	22	22	20	5	4.7
31	B54788	55/M	15.3	15.3	7000	8800	64	66	31	32	2	1	2	1	1	0	10	22	22	17	5	5.1
32	J96682	55/M	13.9	13.7	6900	7200	68	70	30	27	3	1	2	1	0	1	10	22	11	24	4.8	4.7
33	F012801	63/F	13.2	13.1	6800	6800	55	60	40	35	3	2	2	2	0	1	20	40	14	25	4.8	4.8
34	D096378	54/F	11.6	11.6	8100	8700	66	64	32	33	2	3	0	0	0	0	30	62	10	20	4	4.2
35	D035254	65/M	16.6	14.4	7900	6700	67	67	29	26	3	4	1	2	0	1	2	4	4	10	5.5	4.8
36	I16137	44/M	15	14.6	8000	7300	60	64	37	34	3	2	0	0	0	0	16	32	8	16	5	4.9
37	H18530	64/M	15	15.2	6900	7200	67	65	26	35	3	2	2	2	2	1	4	12	10	22	5	5.2
38	E43506	55/F	13.2	14	7800	7100	65	60	30	37	3	2	2	1	0		20	19	22	18	4.8	4.9
39	J94494	49/M	13.7	13.8	7500	8600	63	63	35	33	1	1	1	2	0	1	12	20	16	18	4.2	4
40	K00669	41/M	14	14.3	5200	6600	68	65	26	30	3	2	2	2	1	1	14	20	12	22	5.2	5.2

SGOT		SGPT		ALP		U.ACID		UREA		CREAT.		VDRL		HBsAg	
B.TMT	A.TMT	B.TMT	A.TMT	B.TMT	A.TMT	B.TMT	A.TMT	B.TMT	A.TMT	B.TMT	A.TMT	B.TMT	A.TMT	B.TMT	A.TMT
13	15	15	16	90	86	5	3.6	31	26	1.4	1.2	N-R	N-R	NEG	NEG
18	22	13	10	83	78	4.8	4.2	17	18	1.4	0.8	N-R	N-R	NEG	NEG
21	26	41	32	82	65	4.1	4.3	30	22	0.9	0.6	N-R	N-R	NEG	NEG
22	25	28	16	56	60	4.8	3.6	22	17	1.2	1	N-R	N-R	NEG	NEG
15	13	15	13	112	110	4.2	3.9	20	25	1.4	0.9	N-R	N-R	NEG	NEG
11	14	17	16	94	89	3.3	4	18	16	1	0.8	N-R	N-R	NEG	NEG
13	12	18	14	99	56	5.9	5.3	22	26	0.9	0.6	N-R	N-R	NEG	NEG
14	18	13	10	56	70	4.3	3.6	24	30	1.2	1	N-R	N-R	NEG	NEG
12	10	11	19	105	115	4.4	4.6	14	22	1.1	1	N-R	N-R	NEG	NEG
19	21	18	20	110	129	4.3	4.6	17	17	0.9	1	N-R	N-R	NEG	NEG
13	12	9	14	120	90	5.1	5	18	16	0.9	0.9	N-R	N-R	NEG	NEG
35	24	40	36	75	60	7.1	6.2	22	20	1.2	0.8	N-R	N-R	NEG	NEG
13	14	16	7	63	59	4.7	6.1	20	12	1	1.1	N-R	N-R	NEG	NEG
23	19	39	30	65	50	4.9	5.3	28	23	1.1	1.1	N-R	N-R	NEG	NEG
22	15	10	12	72	57	5	4.5	18	17	0.9	0.9	N-R	N-R	NEG	NEG
16	17	20	12	90	89	6	5.8	26	24	0.9	0.9	N-R	N-R	NEG	NEG
16	18	14	19	93	112	5.2	5.6	21	22	1	0.6	N-R	N-R	NEG	NEG
11	14	30	11	128	100	4.8	4.2	31	14	0.6	0.8	N-R	N-R	NEG	NEG
19	27	22	37	75	72	3.7	4.5	13	12	0.8	0.9	N-R	N-R	NEG	NEG
20	24	21	40	55	51	3.2	4.4	22	20	0.5	0.6	N-R	N-R	NEG	NEG
49	34	47	48	88	56	6.9	7.5	23	32	1	1.2	N-R	N-R	NEG	NEG
30	25	34	14	65	89	4.6	4.2	14	12	0.9	0.8	N-R	N-R	NEG	NEG
29	22	24	22	64	69	4.9	4.8	24	27	0.8	0.7	N-R	N-R	NEG	NEG
10	10	15	13	117	95	5.1	6.6	14	22	0.8	0.9	N-R	N-R	NEG	NEG
15	16	14	10	92	86	5.2	4.6	26	22	0.9	1.2	N-R	N-R	NEG	NEG
17	14	11	13	54	65	3.6	4	15	22	1	1.1	N-R	N-R	NEG	NEG
11	16	14	16	36	87	3.2	4	20	18	0.8	0.6	N-R	N-R	NEG	NEG
24	24	25	25	28	24	4.2	3.8	11	10	1.1	1	N-R	N-R	NEG	NEG
21	20	23	19	49	54	3.6	4.6	21	18	1.2	1.2	N-R	N-R	NEG	NEG
16	14	9	8	103	159	5.7	5.3	23	14	1	1	N-R	N-R	NEG	NEG
4	13	15	21	16	20	6.2	5.6	35	36	0.9	1	N-R	N-R	NEG	NEG
12	8	13	8	71	72	5.6	4.2	22	27	1	1.1	N-R	N-R	NEG	NEG
17	14	20	10	86	72	4.2	3.6	23	15	1	1.1	N-R	N-R	NEG	NEG
18	16	10	10	78	56	4.6	4.2	19	21	1	1	N-R	N-R	NEG	NEG
17	16	18	15	89	72	3.3	3.9	24	27	1.2	1.5	N-R	N-R	NEG	NEG
13	17	25	22	88	70	6.9	7	27	21	1.1	1.2	N-R	N-R	NEG	NEG
17	13	23	22	74	80	3.5	3.2	19	17	0.9	0.8	N-R	N-R	NEG	NEG
15	16	24	25	79	81	3.9	4.2	25	18	0.8	0.7	N-R	N-R	NEG	NEG
22	30	22	28	101	98	4.5	4.4	24	22	1.2	0.8	N-R	N-R	NEG	NEG
28	25	24	21	87	85	5	5.1	15	26	0.9	1	N-R	N-R	NEG	NEG

S.NO	OP NO.	AGE/SEX	T.CHOLESTEROL		HDL		LDL		VLDL		TGL		T.BIL		D.BIL		I.BIL	
			B.TMT	A.TMT	B.TMT	A.TMT	B.TMT	A.TMT	B.TMT	A.TMT	B.TMT	A.TMT	B.TMT	A.TMT	B.TMT	A.TMT	B.TMT	A.TMT
1	K01268	40/M	166	160	33	35	100	78	81	61	405	306	1.3	1	0.4	0.6	0.9	0.4
2	K04833	63/M	208	180	44	50	128	110	25	26	125	131	0.6	0.8	0.2	0.4	0.4	0.4
3	K10295	44/M	190	167	45	57	107	98	14	16	72	80	0.6	0.9	0.2	0.5	0.4	0.4
4	H40537	61/M	232	222	58	56	154	142	23	23	118	116	0.9	0.5	0.3	0.2	0.6	0.3
5	F83285	51/F	256	235	45	62	159	132	51	49	254	249	0.8	0.5	0.4	0.2	0.4	0.4
6	J64562	53/F	191	188	47	49	106	92	32	32	159	160	0.5	1.1	0.2	0.6	0.3	0.5
7	J63805	54/M	198	170	45	48	102	101	48	46	242	230	0.4	0.8	0.1	0.2	0.3	0.6
8	H62039	57/M	190	165	34	42	109	103	29	31	146	154	0.6	0.5	0.2	0.3	0.4	0.2
9	J48903	43/F	183	160	46	50	93	100	23	25	116	126	0.3	0.6	0.1	0.2	0.2	0.4
10	I29424	64/M	161	195	45	56	83	104	19	20	93	101	1	0.7	0.6	0.3	0.4	0.4
11	H09512	51/F	140	145	50	61	74	83	15	18	74	85	0.3	0.7	0.1	0.5	0.2	0.2
12	G94161	56/F	183	180	50	54	100	125	21	16	103	110	0.3	0.4	0.1	0.3	0.2	0.1
13	H7542	65/M	185	173	41	40	89	94	32	35	162	175	0.5	0.7	0.2	0.3	0.3	0.4
14	H08942	55/M	196	204	51	57	133	111	25	27	125	138	0.7	0.6	0.3	0.2	0.4	0.4
15	K03811	57/F	243	230	43	46	166	136	29	36	144	179	1.1	0.7	0.6	0.2	0.5	0.5
16	K08232	60/F	221	251	52	55	127	141	34	49	169	247	0.8	0.7	0.3	0.2	0.5	0.5
17	G14501	48/M	180	160	44	50	114	120	27	28	134	138	0.8	1	0.3	0.6	0.5	0.4
18	G90895	53/F	190	182	48	52	142	97	64	51	320	256	0.7	0.6	0.4	0.2	0.3	0.4
19	F93255	49/F	236	211	72	58	138	121	44	24	220	122	0.6	0.7	0.2	0.3	0.4	0.4
20	J90011	55/M	222	190	67	38	112	110	47	51	200	198	0.7	0.6	0.2	0.3	0.4	0.3
21	J74644	63/M	161	178	40	40	100	102	47	44	238	220	0.6	0.6	0.2	0.2	0.4	0.4
22	G88341	65/F	177	160	57	56	109	116	20	26	98	130	0.8	0.7	0.4	0.4	0.4	0.3
23	K02169	40/M	178	171	45	52	101	120	28	37	216	194	0.7	0.7	0.3	0.3	0.5	0.4
24	J73310	41/M	197	188	37	45	110	104	71	43	355	217	0.5	0.5	0.1	0.2	0.4	0.4
25	J39989	52/F	211	198	59	55	114	118	27	31	137	156	0.6	0.6	0.2	0.3	0.4	0.3
26	G81362	43/M	135	170	41	44	75	96	14	23	73	116	0.9	1.1	0.3	0.4	0.6	0.7
27	J69262	38/F	183	152	47	45	120	113	17	16	88	78	1.3	1	0.4	0.5	0.8	0.5
28	I1498	60/M	165	144	54	52	146	165	29	28	145	142	0.9	0.9	0.3	0.3	0.6	0.6
29	G95705	49/M	150	165	52	50	125	100	27	25	132	125	0.6	0.6	0.2	0.3	0.4	0.3
30	J54520	60/M	190	182	74	61	102	95	14	1	71	81	0.7	0.7	0.3	0.3	0.4	0.4
31	B54788	55/M	145	150	58	56	98	86	40	30	200	150	0.6	0.8	0.2	0.3	0.4	0.5
32	J96682	55/M	213	169	44	42	56	66	27	29	135	144	0.5	0.6	0.1	0.2	0.4	0.4
33	F012801	63/F	187	168	46	44	56	53	19	12	95	89	0.3	0.3	0.1	0.1	0.2	0.2
34	D096378	54/F	145	126	38	36	78	83	26	25	132	123	0.4	0.5	0.2	0.2	0.2	0.3
35	D035254	65/M	117	126	46	40	66	63	35	28	174	141	1	1.2	0.4	0.5	0.6	0.7
36	I16137	44/M	212	223	44	38	143	132	62	95	313	476	1	1.5	0.3	0.4	0.7	1.1
37	H18530	64/M	155	160	40	45	84	80	28	24	140	147	0.8	1	0.3	0.2	0.5	0.5
38	E43506	55/F	118	124	39	37	66	63	26	25	173	130	0.7	0.5	0.3	0.1	0.4	0.5
39	J94494	49/M	210	201	42	50	64	75	64	55	204	208	1	1	0.4	0.1	0.6	0.4
40	K00669	41/M	154	167	54	52	78	84	25	26	165	179	0.8	1	0.3	0.2	0.3	0.5

URINE ANALYSIS													
ALB		SUG(F)		SUG(PP)		PUS		EPI		NEERKURI		NEIKURI	
B.TMT	A.TMT	B.TMT	A.TMT	B.TMT	A.TMT	B.TMT	A.TMT	B.TMT	A.TMT	B.TMT	A.TMT	B.TMT	A.TMT
NIL	NIL	++	+	++	+	3-5	1-2	3-5	1-2	Pale yellow	Pale yellow	Pearl	Pearl
NIL	NIL	NIL	NIL	NIL	NIL	2-4	1-2	1-2	1-2	Yellow	Yellow	Round	Round
NIL	NIL	+	+	+	NIL	4-5	2-4	2-4	3-5	Yellow	Yellow	Round	Round
NIL	NIL	NIL	NIL	+	NIL	1-2	0-1	1-2	1-3	Pale yellow	Pale yellow	Pearl	Pearl
NIL	NIL	NIL	NIL	NIL	NIL	1-2	1-2	1-2	1-2	Pale yellow	Colourless	Round	Round
NIL	NIL	NIL	NIL	+	NIL	1-2	0-1	1-2	1-3	Pale yellow	Pale yellow	Round	Pearl
TRACE	NIL	NIL	NIL	+	+	1-2	3-4	6-8	1-2	Yellow	Yellow	Irregular	Round
NIL	NIL	NIL	NIL	NIL	NIL	2-4	2-4	5-6	3-4	Yellow	Dark yellov	Round	pearl
NIL	NIL	NIL	NIL	NIL	NIL	9-10	2-4	7-8	1-2	Pale yellow	Pale yellow	Pearl	Pearl
+	NIL	NIL	NIL	++	NIL	10-12	2-4	2-4	2-4	Yellow	Yellow	Round	Round
NIL	NIL	NIL	NIL	NIL	NIL	1-2	1-2	1-2	1-2	Yellow	Dark yellov	Round	pearl
NIL	NIL	NIL	NIL	NIL	NIL	1-2	1-2	1-2	1-2	Colouless	Yellow	Irregular	Round
NIL	NIL	NIL	NIL	++	NIL	2-4	1-2	1-2	1-2	Pale yellow	Pale yellow	Pearl	Pearl
NIL	NIL	Trace	+	++	++	4-6	1-2	6-8	1-2	Yellow	Yellow	Pearl	Round
NIL	NIL	NIL	NIL	NIL	NIL	2-4	2-4	4-6	2-4	Pale yellow	Pale yellow	Pearl	Pearl
NIL	NIL	NIL	NIL	NIL	NIL	1-2	1-2	1-2	1-2	Pale yellow	Pale yellow	Pearl	Pearl
NIL	NIL	NIL	NIL	++	++	1-2	5-5	1-2	1-2	Yellow	Yellow	Round	Round
NIL	NIL	NIL	NIL	NIL	NIL	1-2	1-2	1-2	1-2	Pale yellow	Pale yellow	Round	Round
NIL	NIL	NIL	NIL	+++	NIL	2-4	Plenty	2_4	10_15	Pale yellow	Pale yellow	Round	Irregular
NIL	NIL	NIL	NIL	++	Trace	4-6	2_3	4-6	1_2	Pale yellow	Pale yellow	Pearl	Pearl
NIL	NIL	NIL	NIL	++	NIL	1_2	1_2	4_6	2_4	Yellow	Yellow	Irregular	Irregular
NIL	NIL	NIL	NIL	+	NIL	2_4	0_1	2_4	1_2	Yellow	Yellow	Round	Round
NIL	NIL	NIL	NIL	NIL	NIL	2_4	1_2	2_4	1_2	Colouless	Yellow	Pearl	Pearl
NIL	NIL	++	+	NIL	NIL	6_8	2_4	1_2	0_1	Dark yellov	Dark yellov	Ring	Ring
NIL	NIL	NIL	NIL	NIL	NIL	2-4	6-8	1_2	1_2	Pale yellow	Yellow	Slowly spre	Round
NIL	NIL	NIL	NIL	++	NIL	1_2	2_4	5_10	2_4	Yellow	Pale yellow	Round	Pearl
NIL	NIL	NIL	NIL	NIL	NIL	1_2	1_2	1_2	1_2	Pale yellow	Pale yellow	Round	Pearl
NIL	NIL	NIL	NIL	+	NIL	2_3	1_2	1_2	1_2	Pale yellow	Pale yellow	Round	Pearl
NIL	NIL	NIL	NIL	NIL	NIL	1_2	1_2	1_2	0_1	Pale yellow	Colourless	Pearl	Pearl
NIL	NIL	NIL	NIL	+++	++	1_2	1_2	2-4	1_2	Yellow	Yellow	Pearl	Round
NIL	NIL	+	NIL	++	++	1_2	2_3	3_4	2_3	Pale yellow	Yellow	Pearl	Round
NIL	Trace	NIL	NIL	NIL	NIL	1_2	1_3	1_2	4_6	Yellow	Colourless	Pearl	Round
NIL	NIL	NIL	NIL	NIL	NIL	1_2	1_2	1_2	1_2	Pale yellow	Pale yellow	Pearl	Pearl
NIL	NIL	NIL	NIL	++	+++	2_4	3_5	2_4	1_2	Yellow	Yellow	Pearl	Pearl
NIL	NIL	NIL	NIL	+	+	1_3	2_4	1_3	1_2	Yellow	Colourless	Pearl	Pearl
NIL	NIL	NIL	NIL	NIL	NIL	1-2	1-2	1-2	1-2	Pale yellow	Pale yellow	Pearl	Pearl
NIL	NIL	NIL	NIL	++	++	1-2	5-5	1-2	1-2	Yellow	Yellow	Round	Round
NIL	NIL	NIL	NIL	NIL	NIL	1_2	1_2	1_2	1_2	Pale yellow	Pale yellow	Round	Pearl
NIL	NIL	NIL	+	NIL	NIL	2_3	1_2	1_2	1_2	Pale yellow	Pale yellow	Round	Pearl
NIL	NIL	NIL	NIL	NIL	NIL	2-4	2-4	4-6	2-4	Pale yellow	Pale yellow	Pearl	Pearl

BIBLIOGRAPHY

1. Shanmugavelu M, Noi naadal noimudhalnaadal Part I Pub: Directorate of of Indian medicine and Homeopathy, Chennai.

2. Thyagarajan.R.Siddha Maruthuvam Sirappu.3rd Edition,Commissionerate of Indian Medicine and Homoeopathy,Chennai,2008

3. Uthamarayan C.S. Siddha Maruthuvanga Churukkam. 2nd Edition, Depatment of Indian Medicine and Homoeopathy,Chennai.

4. Shanmugavelu.Siddha Maruthuva Noi Naadal Noi Mudhal Naadal Thirattu (part- 1). 1st Edition.Tamilnadu Siddha Maruthuva Variya Veliyeedu 1987.

5. Kuppuswamy Mudhaliyar.Siddha Maruthuvam (Podhu).6th Edition.Department of Indian Medicine and Homoeopathy,Chennai-106, 2004

6. Yugivaidhyachinthamani, Ugimunivar, Department of Indian medicine and Homoeopathy,Chennai-106, Second edition, 2005

7. Kannuswamy Pillai,Sikitcha Rathna Deepam Ennum Vaithya Nool, 2nd Edition.

8. N.Kandasamy Pillai; History of Siddha Medicine; Department of Indian Medicine and Homoeopathy,Chennai-106

9. Agathiyar – 1200, First edition, may 1997.

10. Agathiyar gunavagadam

11. Marundhu sei Eyalum kalayum. A.Sundhararajan P.No:283.

12. T.V. Sambasivam pillai, Introduction to Siddha Medicine, Second edition,1998 Thirumoolar Ashtanga yoga –a therapeutic approach of good health- Dr.Asana andiyappan ,first edition 2009.

13. Anandha rahasyam-Yogacharya twenty eighth edition 2003,The yoga publisihing house,bengalure

14. ThirumoolarThirumanthiram; GangaiPuthagaNilayam1st Edition May 2002

15. Tamil-English dictionary, T.V.Sambasivampillai

16. Dr.C.S.Uthamaroyan, A Compendium of Siddha Doctrine, First edition,2005.

17. Thearaiyar Neerkuri & Neikuri, First edition , June 2000

18. Hutchinson's Clinical Methods, 21st edition, 2003.

19. Harrison's Principles of Internal Medicine, Sixteenth edition

20. Davidson's textbook of medicine, 19 th edition.

21. K.D.Tripathi, Essentials of Medical Pharmocology, Fifth edition, 2003.

22. OECD, OECD Guideline for Testing of Chemicals,Acute Oral Toxicity-Acute Toxic Class Method:TG 423-Adopted, OECD, Paris, France, 2001. 93.

23. OECD, OECD Guideline for Testing of Chemicals,Repeated Dose 28-day Oral Toxicity Study inRodents: TG 408-Adopted, OECD, Rome,1981.

24. Studies on the aqueous extract of Terminalia chebula as a potent antioxidant and a probable radioprotector.

25. Naik GH, Priyadarsini KI, Naik DB, Gangabhagirathi R, Mohan HPhytomedicine. 2004 Sep; 11(6):530-8.

26. Kannan VR, Rajasekar GS, Rajesh P, Balasubramanian V, Ramesh N, Solomon EK, et al. et al. Anti-diabetic activity on ethanolic extracts of fruits of *Terminalia chebula* Retz. Alloxan induced diabetic rats. Am J Drug Discov Dev. 2012;2:135–142.

27. Gandhipuram Periasamy Senthilkumar, Sorimuthu Pillai Subramanian, Biochemical studies on the effect of Terminalia chebula on the levels of glycoproteins in streptozotocin-induced experimental diabetes in rats, J. Appl. Biomed. 2008, 6, 105–115.

28. Warrier PK, Nambiar VP, Ramankutty C. Indian Medicinal Plants: A Compendium of 500 Species

29. Antidiabetic effect ofT. arjuna bark extract in alloxan induced diabetic ratsB. Ragavan and S. Krishnakumari Indian Journal of Clinical Biochemistry, 2006 / 21 (2) 123-128

30. Amit Gupta* and Sushama R. Chaphalkar haemolytic activities and antidiabetic effect of terminalia arjuna and emblica officinalis. European journal of pharmaceutical and medical research ejpmr, 2016,3(6), 334-338

31. Sengupta P, Das PB. Terpenoids and related compunds part IV triterpenoids the stem-bark of *Eugenia jambolana* Lam. Indian Chem Soc. 1965;42:255–258

32. Tripathi AK, Kohli S. Pharmacognostical standardization and antidiabetic activity of *Syzygium cumini* (Linn.) barks (Myrtaceae) on streptozotocin-induced diabetic rats. Complement Integr Med. 2014; 11(2):71-81

33. Chempakam B., Hypoglycemic activity of arecoline in betel nut Areca catechu L., Ind. J of Exp. Biol, 31 (5), 1993, 474-475

34. Inokuchi J, Okabe H, Yamauchi T et al, Antihypertensive substance in seeds of Areca catechu Linn., Life Sci, 38,1986, 1375– 1382.

35. Kar A, Choudhary BK, Bandyopadhyay NG, Comparative evaluation of hypoglycaemic activity of some Indian Medicinal Plants in alloxan diabetic rats, J Ethnopharmacol, 4, 2003, 105-108

36. Jahan IA, Nahar N, Mosihuzzaman M, Hypoglycaemic and antioxidant activities of Ficus racemosa Linn. Fruits, Nat Prod Res, 23, 2008, 399-408.

37. Chopra RN, Chopra IC, Handa KL, Kapur LD (1958): *Indigenous Drugs of India*, second edition. Calcutta, Academic Publishers, pp. 508–674.

38. Matsuda HYM, Morikawa T, Tanabe G, Muraoka O. Antidiabetogenic constituents from Salacia species. J Trad Med. 2005;22(1):145–53

39. Shimoda HKS, Kawahara Y. Effects of an aqueous extract of Salacia reticulata, a useful plant in Sri Lanka, on postprandial hyperglycaemia in rats and humans. J Jpn Soc Nutr Food Sci. 1998;51:279–89. doi: 10.4327/jsnfs.51.279

40. Yoshikawa MMT, Yashiro K, Matsuda H. Katalanol a potent alpha glucosidase inhibitor with thiosugar sulfonium silphate structure from antidiabetic Ayurvedic medicine Salacia reticulata. Chem Pharm Bull. 1998;46(8):1339–40. doi: 10.1248/cpb.46.1339.

41. Yoshikawa MNN, Shimoda H, Takada M. Polyphenol constituents from Salacia species: quantitative analysis of mangiferin with alpha glucosidase and aldose reductase inhibitory activities. Yakugaku Zasshi. 2001;121:5371–8. doi: 10.1248/yakushi.121.371

42. Shimoda HKS, Kawahara Y. Effects of an aqueous extract of Salacia reticulata, a useful plant in Sri Lanka, on postprandial hyperglycaemia in rats and humans. J Jpn Soc Nutr Food Sci. 1998;51:279–89. doi: 10.4327/jsnfs.51.279.

43. Dhasarathan P, Theriappan P. Evaluation of antidiabetic activity. J Medicine Medical Sci 2011; 2(2): 670-674.

44. Ekambaram SP, Perumal SS, Subramanian V. Evaluation of antiarthritic activity of *Strychnos potatorum* Linn seeds in Freund's adjuvant induced arthritic rat model. BMC Complement Altern Med. 2010;10:56.

45. Nadkarni KM. The Indian Plants and Drugs. New Delhi: Shrishti Book Distributors, 2005, 4, 5

46. Singh B N , Singh BR , Singh RL, Prakash D, Sarma BK, Singh HB . Antioxidant and antiquorum sensing activities of green pod of Acacia nilotica L., Food and Chemical Toxicology 2009; 47: 778–786. 49.

47. Kalaivani T, Mathew Lazar. Free radical scavenging activity from leaves of Acacia nilotica (L.) Wild. ex Delile,an Indian medicinal tree, Food and Chemical Toxicology

48. Ramesh Kumar, Chauhan PK, Bhardwaj VS, Anu Kumar Munish kumar. In vitro investigations of antioxidant and phytochemical activities of aqueous extracts of Terminalia belerica & Terminalia chebula International Journal of Research in Pharmaceutical and Biomedical Sciences.

49. .Singh R, Singh B, Singh S , Kumar N, Kumar S , Arora S. Umbelliferone – An antioxidant isolated from Acacia nilotica (L.) Willd. Ex. Del., Food Chemistry 2009.

50. Priya G, Parminder N and Jaspreet S (2012). Antimicrobial and antioxidant activity on Emblica officinalis seed extract. Int. J. Res. Ayur. Pharma. 3(4): 591-596

51. Jayaweera, D.M.A.: Medicinal Plants used in Ceylon Part 2. National Science Council of Sri Lanka. Colombo 1980

52. M C Sabu & Ramadasan Kuttan ,Antidiabetic and antioxidant activity of Terminalia belerica. Roxb. Indian Journal of Experimental Biology Vol. 47, April 2009, pp. 270-275

53. P. Daisy*and Feril G. Jeeva kaniEvaluation of antidiabetic activity of various extracts of cassia auriculata linn. Bark on streptozotocin- induced diabetic wistar rats.International Journal of Pharmacy and Pharmaceutical Sciences.

54. Kolar, Firdose & L. Gogi, Chaya & M. Khudavand, Mairunisabegum & S. Choudhari, Meera & B. Patil, Sindhu. (2017). Phytochemical and antioxidant properties of some Cassia species. Natural Product Research. 32. 1-5. 10.1080/14786419.2017.1342085.

NATIONAL INSTITUTE OF SIDDHA,
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CHENNAI 47.

DEPARTMENT OF SIRAPPU MARUTHUVAM

"PRECLINICAL AND COMPARATIVE CLINICAL STUDY OF MARUTHAMPATTAI KUDINEER AND YOGAM THERAPY IN THE MANAGEMENT OF MADHUMEGAM (TYPE II DIABETES)

FORM-l (SCREENING & SELECTION PROFORMA)

1. **SI NO: _____**
2. **OP/IP NO: _____**
3. **NAME:_____**
4. **RELIGION: H/C/M/O**
5. **AGE: _____**
6. **GENDER: _____**

INCLUSION CRITERIA

- Age : 30-65 years YES/NO
- Gender: Male/ Female

With symptoms of

- Polyuria,Polydipsia,Nocturia,Polyphagia YES/NO
- Blood glucose level:
  - Fasting plasma blood glucose level-≤ 150 mg/dl YES/NO
  - Two Hours postprandial plasma blood glucose level- ≤250 mg/dl YES/NO
  - Glycosylated haemoglobin (HbA1c) ≤ 8% YES/NO

- Non Insulin Dependent Diabetes Mellitus YES/NO

EXCLUSION CRITERIA

- Fasting plasma blood glucose level- >151 mg/dl YES/NO
- 2 Hours postprandial plasma blood glucose level- >251 mg/dl YES/NO
- Glycosylated haemoglobin (HbA1c)- > 8.1% YES/NO
- Patient with diabetic complications diabetic foot, retinopathy etc., YES/NO
- Insulin Dependent Diabetes Mellitus YES/NO

- Any other serious Systemic Diseases YES/NO
- Pregnancy and lactation YES/NO

ADMITED TO TRAIL Yes /No If Yes, Serial NO: _____

DATE: STATION:

SIGNATURE OF THE INVESTIGATOR

SIGNATURE OF THE LECTURER

SIGNATURE OF THE HOD

NATIONAL INSTITUTE OF SIDDHA,
AYOTHIDASS PANDITHAR HOSPITAL,
CHENNAI 47.
DEPARTMENT OF SIRAPPU MARUTHUVAM

PRECLINICAL AND COMPARATIVE CLINICAL STUDY OF

MARUTHAMPATTAI KUDINEER AND YOGAM THERAPY IN THE

MANAGEMENT OF MADHUMEGAM (TYPE II DIABETES)

FORM II-CASE RECORD FORM

STUDY NO: **OP / IP NO:**

NAME: **AGE / GENDER:**

ADDRESS: **CONTACT NO :**

RELIGION : H / C / M / O.

OCCUPATION: **INCOME:**

MARITAL STATUS : 1. Married ☐ 2. Unmarried ☐

DATE OF INTIAL ASSESSMENT:

COMPLAINTS & DURATION:

PERSONAL HISTORY:

PERSONAL HABITS	YES	NO	IF YES SPECIFY DURATION	AMOUNT/Quantity
Smoking				
Tobacco Chewing				
Alcohol				
Narcotic Drug Addiction				

HISTORY OF PREVIOUS ILLNESS AND TREATMENT TAKEN:
FAMILY HISTORY:

Whether this problem runs in family? 1. Yes 2. No

If yes, mention the relationship of affected person(s) 1._____

2._____

DIETARY STYLE: 1. Vegetarian 2. Non-vegetarian

MENSTURAL AND OBSTETRIC HISTORY

FORM II B

GENERAL EXAMINATION

1. Body weight [Kg] :
2. Height [cms] :
3. Body Temperature [F] :
4. Blood Pressure (mm/Hg) :
5. Pulse Rate /min. :
6. Heart Rate / min. :
7. Respiratory Rate /min. :

		Yes	**No**
8. Pallor	:	☐	☐
9. Jaundice	:	☐	☐
10. Clubbing	:	☐	☐
11. Cyanosis	:	☐	☐
12. Pedal Oedema	:	☐	☐
13. Lymphadenopathy	:	☐	☐
14. Jugular venous pulsation	:	☐	☐

SYSTEMIC EXAMINATION

Cardiovascular system :

Respiratory system :

Gastro-intestinal system :

Central Nervous system :

Urogenital system :

SIDDHA SYSTEM OF EXAMINATION:

1. Vathaudal ☐
2. Pithaudal ☐
3. Kabaudal ☐
4. Thonthaudal ☐

2. NILAM (LAND WHERE THE PATIENT LIVED MOST):

1. Kurinji(Hilly terrain) ☐
2. Mullai (Forest range) ☐
3. Marutham (Plains) ☐
4. Neithal (Coastal belt) ☐
5. Paalai (Aridregion) ☐

3. KAALAM:

1. Kaarkaalam (Aavani-Purattasi) ☐
2. Koothirkaalam (Ippasi-Kaarthigai) ☐
3. Munpanikaalam (Maargazhi-Thai) ☐
4. Pinpanikaalam (Maasi-Panguni) ☐
5. Ilavenilkaalam (Chithirai-Vaigasi) ☐
6. Muthuvenilkaalam (Aani-Aadi) ☐

4. GUNAM:

1. Sathuvam ☐
2. Rasatham ☐
3. Thamasam ☐

5. PORIPULANGAL (SENSORY ORGANS):

	Before treatment	**After treatment**
Mei (Skin)	Normal / Affected	Normal / Affected
Vai (Tongue)	Normal / Affected	Normal / Affected
Kann (Eye)	Normal / Affected	Normal / Affected
Mooku (Nose)	Normal / Affected	Normal / Affected
Sevi (Ear)	Normal / Affected	Normal / Affected

6.KANMENDRIYAM (MOTOR ORGANS) :

	Before treatment	**After treatment**
Kai (Upper limb)	Normal /Affected	Normal /Affected
Kaal(Lower limb)	Normal /Affected	Normal /Affected
Vai(Oral cavity)	Normal /Affected	Normal /Affected
Eruvai(Anal region)	Normal /Affected	Normal /Affected
Karuvai (Uro-Genital region)	Normal /Affected	Normal /Affected

7. KOSANGAL (SHEATH):

	Before treatment	**After treatment**
Annamayakosam	Normal /Affected	Normal /Affected
Pranamayakosam	Normal /Affected	Normal /Affected
Manomayakosam	Normal /Affected	Normal /Affected
Vignanamayakosam	Normal /Affected	Normal /Affected
Ananthamayakosam	Normal /Affected	Normal /Affected

8. SEVEN UDAL THAATHUKKAL (SEVEN SOMATIC COMPONENTS)

	Before treatment	**After treatment**
Saaram	Normal /Affected	Normal /Affected
Senneer	Normal /Affected	Normal /Affected
Oon	Normal /Affected	Normal /Affected
Kozhuppu	Normal /Affected	Normal /Affected
Enbu	Normal /Affected	Normal /Affected
Moolai	Normal /Affected	Normal /Affected
Sukkilam / Suronitham	Normal /Affected	Normal /Affected

9. UYIR THAATHUKKAL: [THREE HUMORS] (VALI/ AZHAL/ IYYAM)

A) VALI

	0th day	8th day	15th day	22nd day	29th day	36th day	43rd day	49th day	56th day	63th day	70th day	77th day	84th day	90th day
Praanan														
Abaanan														
Samaanan														
Udhaanan														
Viyaanan														
Naagan														
Koorman														
Kirukaran														
Devathathan														
Dhananjeyan														

B) AZHAL

	0th day	8th day	15th day	22nd day	29th day	36th day	43rd day	49th day	56th day	63th day	70th day	77th day	84th day	90th day
Anarpitham														
Ranjagapitham														
Prasagam														
Aalosagam														
Sathagam														

C) IYYAM

	0th day	8th day	15th day	22nd day	29th day	36th day	43rd day	49th day	56th day	63th day	70th day	77th day	84th day	90th day
Avalambagam														
Klethagam														
Pothagam														
Tharpagam														
Santhigam														

10. ENVAGAI THERVU: [EIGHT TYPES OF EXAMINATION]

I. NAADI: [PULSE PERCEPTION]

	0th day	8th day	15th day	22nd day	29th day	36th day	43rd day	49th day	56th day	63th day	70th day	77th day	84th day	90th day
Naadi														

II SPARISAM: [PALPATION]

	0th day	8th day	15th day	22nd day	29th day	36th day	43rd day	49th day	56th day	63th day	70th day	77th day	84th day	90th day
Sparisam														

III.NAA: [TONGUE]

	0th day	8th day	15th day	22nd day	29th day	36th day	43rd day	49th day	56th day	63th day	70th day	77th day	84th day	90th day
Naa														

IV. NIRAM: [COMPLEXION]

1. Vadham ☐

2. Pitham ☐

3. Kabam ☐

V. MOZHI: [VOICE]

1. High Pitched ☐

2. Low Pitched ☐

3. Medium Pitched ☐

VI.VIZHI: [EYES]

	0th day	**8th day**	**15th day**	**22nd day**	**29th day**	**36th day**	**43rd day**	**49th day**	**56th day**	**63th day**	**70th day**	**77th day**	**84th day**	**90th day**
VIZHI														

VII. MALAM: [BOWEL HABITS / STOOLS]

	Before treatment	**After treatment**
Niram		
Irugal		
Ilagal		
Others		

VIII. MOOTHIRAM [URINE EXAMINATION]

NEERKKURI:

Neerkkuri	Before treatment	After treatment
Niram		
Manam		
Edai		
Nurai		
Enjal		

NEIKKURI:

Neikkuri	Before treatment	After treatment
Aravananeedathu/ Snake like pattern		
Azhipolparaviyathu Annular/Ringedpattern		
Muththothuninrathu Pearlbeadepattern		
Other patterns		

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.

DEPARTMENT OF SIRAPPU MARUTHUVAM

PRECLINICAL AND COMPARATIVE CLINICAL STUDY OF MARUTHAM PATTAI KUDINEER AND YOGAM IN THE MANAGEMENT OF MADHUMEGAM (TYPEII DIABETES MELLITUS)

Principal Investigator: Dr. B.Vinubharathi

1. SERIAL NO: 2. OP /IP NO:
3. NAME: 4. AGE/GENDER:

FORM-III - LABORATORY INVESTIGATIONS

BLOOD INVESTIGATIONS		NORMAL VALUES	BEFORE TMT (WITH DATE)	AFTER TMT (WITH DATE)
HB(gm/dl)		M:12-15 W:11.5-14		
T.WBC (cells/cu.mm)		4000-11000		
DIFFERENTIAL COUNT (%)	Polymorphs	40-75		
	Lymphocytes	20-40		
	Monocytes	2-10		
	Eosinophils	1-6		
	Basophils	0-1		
T.RBC(million cells/cu.mm)		M:4.0-5.5 W:3.5-4.5		
ESR(mm/hour)	½ hr.	M:6-12 W:7-18		
	1 hr.			

Blood Investigations		Normal Values	Before Treatment (With Date)	After Treatment (With Date)
Blood glucose (mg/dl)	Fasting	70-110		
	PP	80-140		
	HbA1c	< 6		
RFT (mg/dl)	Blood urea	16-50		
	Serum creatinine	0.6-1.2		
LFT (mg/dl)	Total bilirubin	0.2-1.2		
	Direct bilirubin	0.1-1.2		
	Indirect bilirubin	0.2-0.7		
	SGOT	0-40		
	SGPT	0-35		
	Alkaline phosphatase	80-290		

Urine investigation	Before TMT(with Date)	After TMT (With Date)
Neer kuri		
Nei kuri		
Albumin		
Fasting sugar		
PP sugar		
Deposits		

VDRL

HBSAG:

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer: Signature of the HOD

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.

DEPARTMENT OF SIRAPPU MARUTHUVAM

PRECLINICAL AND COMPARATIVE CLINICAL STUDY OF MARUTHAMPATTAI KUDINEER AND YOGAM THERAPY IN THE MANAGEMENT OF MADHUMEGAM (TYPE II DIABETES)

Principal Investigator: Dr. B.Vinubharathi

FORM –VI- DRUG COMPLIANCE FORM

SERIAL NO:

NAME:

DRUG NAME:

On 1st day-Date: Drugs issued: (Gms) Drugs returned: (Gms)
On 8th day-Date: Drugs issued: (Gms) Drugs returned: (Gms)
On 15th day-Date: Drugs issued: (Gms) Drugs returned: (Gms)
On 22th day-Date: Drugs issued: (Gms) Drugs returned: (Gms)
On 29th day-Date: Drugs issued: (Gms) Drugs returned: (Gms)
On 36th day-Date: Drugs issued: (Gms) Drugs returned: (Gms)
On 43th day-Date: Drugs issued: (Gms) Drugs returned: (Gms)
On 49th day-Date: Drugs issued: (Gms) Drugs returned: (Gms)
On 56th day-Date: Drugs issued: (Gms) Drugs returned: (Gms)
On 63rd day-Date: Drugs issued: (Gms) Drugs returned: (Gms)
On 70th day-Date: Drugs issued: (Gms) Drugs returned: (Gms)
On 77th day-Date: Drugs issued: (Gms) Drugs returned: (Gms)
On 84th day-Date: Drugs issued: (Gms) Drugs returned: (Gms)
On 90th day-Date: Drugs issued: (Gms) Drugs returned: (Gms)

Day	Date	Morning	Evening	Day	Date	Morning	Evening
Day 1				Day46			
Day2				Day47			
Day3				Day48			
Day4				Day49			
Day5				Day50			
Day6				Day51			
Day7				Day52			
Day8				Day53			

Day9				Day54			
Day10				Day55			
Day11				Day56			
Day12				Day57			
Day13				Day58			
Day14				Day59			
Day15				Day60			
Day16				Day61			
Day17				Day62			
Day18				Day63			
Day19				Day64			
Day20				Day65			
Day21				Day66			
Day22				Day67			
Day23				Day68			
Day24				Day 69			
Day25				Day70			
Day26				Day71			
Day27				Day72			
Day28				Day73			
Day29				Day74			
Day30				Day 75			
Day31				Day 76			
Day32				Day77			
Day33				Day78			
Day34				Day79			
Day35				Day80			
Day36				Day81			
Day37				Day82			
Day38				Day83			
Day39				Day84			
Day40				Day85			
Day41				Day86			
Day42				Day87			
Day43				Day88			
Day44				Day89			
Day45				Day90			

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer: **Signature of the HOD**

NATIONAL INSTITUTE OF SIDDHA

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CHENNAI – 600 047.

DEPARTMENT OF SIRAPPU MARUTHUVAM

PRECLINICAL AND COMPARATIVE CLINICAL STUDY OF MARUTHAMPATTAI KUDINEER AND YOGAM THERAPY IN THE MANAGEMENT OF MADHUMEGAM (TYPE II DIABETES)

FORM V– PATIENT INFORMATION SHEET

Name of Principal Investigator: Dr.B.Vinubharathi

Name of the institute: National Institute of Siddha,
Tambaram Sanatorium,
Chennai-47.

INFORMATION SHEET FOR PATIENTS PARTICIPATING IN THE OPEN CLINICAL TRIAL.

I, Dr.B.Vinubharathi,studying M.D (Siddha) at National Institute of Siddha, Tambaram Sanatorium is going to do a trial on "*Madhumegam*" (Diabetes).Diabetes mellitus is a condition where the body fails to utilize the ingested glucose properly. It is a metabolic disorder and caused by lack of the insulin or insufficiency of insulin actions.

In this regard, I am in a need to ask you few questions. I will maintain confidentiality of your comments and data obtained. There will be no risk of disclosing your identity and no physical, psychological or professional risk is involved by taking part in this study. Taking part in this study is voluntary. No compensation will be paid to you for taking part in this study.

You can choose not to take part. You can choose not to answer a specific question. There is no specific benefit for you if you take part in the study. However, taking part in the study may be of benefit to the community, as it may help us to understand the problem of defaulters and potential solutions.

If you agree to be a participant in this study, you will be included in the study primarily by signing the consent form and then you will be given the internal medicine "***MARUTHAM PATTAI KUDINEER*"** (Internal medicine) 60ml bidand '***YOGAM***" (External therapy) for 90 days.

The information I am collecting in this study will remain between you and the principal investigator (I). I will ask you few questions through a questionnaire. I will not write your name on this form. Your name won't be mentioned in the lab investigation form instead a code will be used.

The questionnaire will take approximately 20 minutes of your time.

If you want to know more about this study before taking part, you can contact Dr.B.Vinubharathi, PG Scholar, principal investigator of this study,National Institute of Siddha, Chennai-47. You can also contact the Member-secretary of Ethics committee, National Institute Siddha, Chennai 600047, Tel.No: 91-44-22380789, for rights and participation in the study.

தகவல் படிவம்

தேசிய சித்த மருத்துவ நிறுவனம்
அயோத்திதாஸ் பண்டிதர் மருத்துவமனை
சென்னை-47

மதுமேகம் என்னும் நோய்க்கானமருதம்பட்டைகுடிநீர் சூரணம்(உள் மருந்து) மற்றும் யோகம் (புற மருத்துவம்) சித்த மருந்துகளின் பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான தகவல் படிவம்.

முதன்மை ஆய்வாளர் பெயர்: மருத்துவர்.பா.வினுபாரதி

நிறுவனத்தின் பெயர்: தேசிய சித்த மருத்துவ நிறுவனம்,
தாம்பரம், சானட்டோரியம்,
சென்னை - 47.

தேசிய சித்த மருத்துவ நிறுவனத்தில் பட்ட மேற்படிப்புபயின்றுவரும் நான்(மருத்துவர்-பா.வினுபாரதி), மதுமேகம் நோயில்மருத்துவ ஆராய்ச்சியில் ஈடுபட்டுள்ளேன்.

மதுமேகம்(வகை 2 டயாபிடிஸ் மெல்லிடஸ்) என்னும் வளர்சிதை மாற்றநோயானது கணையம் என்னும் நாளமில்லா சுரப்பியின்இன்சுலின் ஹார்மோன்பயன்பாட்டு தடையின் காரணமாகவோ,இன்சுலின்குறைபாட்டின் காரணமாகவோ அல்லதுஇரண்டின் காரணமாகவோ குருதியில் சர்க்கரையின் அளவு அதிகப்படுத்தும் நோயாகும். இந்நோய் அடிக்கடி சிறுநீரிழிதல், அதிக பசி, அதிக தாகம்,உடல் சோர்வு,அசதி,கால் எரிச்சல் போன்ற குறிகுணங்களை தோற்றுவிக்கும்.

இந்த ஆராய்ச்சி சம்மந்தமாக சில கேள்விகளை கேட்கவும்,தேவயான ஆய்வகபரிசோதனைக்கு தங்களை பரிசோதனைக்கு உட்படுத்தவும் உள்ளேன், அது சம்மந்தமான தங்களது அனைத்துவிவரங்களும் ரகசியமாய் வைக்கபடும் என உறுதி அளிக்கிறேன்.

இதில் பயணப்படி முதலிய எந்த உதவி தொகையும் வழங்கப்படமாட்டாது.

இந்த ஆராய்ச்சியின் போது உடலுக்கு வேறு பாதிப்பு எற்படும் பட்சத்தில் தேசிய சித்த மருத்துவ நிறுவனத்தில் தக்க சிகிச்சை அளிக்கப்படும்.

இந்த ஆராய்ச்சிக்கு தங்களின் விருப்பத்தின் பேரில் உட்படும் பட்சத்தில் மருதம்பட்டைகுடிநீர் சூரணம் உள்மருந்தாக 60மி.லி இருவேளை (காலை, மாலை) உணவுக்கு பின் நாட்கள் உட்கொள்ள வேண்டும்,குறிப்பிட்ட யோக

முறைகளை தினம் ஒரு முறை(30-45 நிமிடம்) பயிற்சி செய்ய வலியுறுத்தப்படும்.

இந்த ஆராய்ச்சியில் நோயினராக சேர்ந்த பிறகு
உங்களுக்குவிருப்பம்இல்லையெனில் எப்போது வேண்டுமானாலும் விலகி
கொள்ளலாம்.
இந்த ஆராய்ச்சியில் சம்மந்தமாக மற்றவிபரங்களுக்கும் நோயின் தன்மை பற்றியும்
முதன்மைஆய்வாளரான மருத்துவர் பா.வினுபாரதி பட்ட மேற்படிப்பாளார்
சிறப்புமருத்துவ துறை) அணுகவும்.கைபேசி எண்:

மேலும் இந்த ஆராய்ச்சிக்கு IEC சான்று பெறபட்டுள்ளது.

மேலும் உணவு முறையில்மருத்துவரால்கூறப்படும் பத்தியம் காக்குமாறு
அறிவுறுத்தப்படுகிறது.

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL,

CHENNAI – 600 047.

DEPARTMENT OF SIRAPPU MARUTHUVAM

"PRECLINICAL AND COMPARATIVE CLINICAL STUDY OF MARUTHAMPATTAI KUDINEER AND YOGAM THERAPY IN THE MANAGEMENT OF MADHUMEGAM (TYPE II DIABETES)"

Principal Investigator: Dr. B.Vinubharathi

FORM-V – CONSENT FORM

"I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction.

I consent voluntarily to participate as a participant in this study and understand that I have the right to withdraw from the study at any time without in any way it affecting my further medical care".

"I have received a copy of the information sheet/consent form".

Date:

Signature of the participant

In case of illiterate participant

"I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm individual has given consent freely."

Date:

Signature of a witness
(Selected by the participant bearing no connection with the survey team)

Left thumb Impression of the Participant

ஒப்புதல் படிவம்

ஆய்வாளரால்-சான்றளிக்கப்பட்டது

தேசிய சித்த மருத்துவ நிறுவனம்,
அயோத்திதாஸ் பண்டிதர் மருத்துவமனை,
சென்னை-47.

மதுமேகம் என்னும் நோய்க்கானமருதம்பட்டைகுடிநீர் சூரணம்(உள் மருந்து) மற்றும் யோகம் சித்த மருந்துகளின் பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான தகவல் படிவம்.

ஒப்புதல் படிவம்-ஆய்வாளரால் சான்றளிக்கப்பட்டுள்ளது

நான் இந்த ஆய்வை குறித்த அனைத்துவிபரங்களையும் நோயளிக்குப்புரியும் வகையில் எடுத்துரைத்தேன் என உறுதியளிக்கிறேன்.

தேதி:

கையொப்பம்:

இடம்: **பெயர்:**

நோயாளியின் ஒப்புதல்

என்னிடம் இந்த மருத்துவ ஆய்வின் காரணத்தையும்,மருந்தின் தன்மை மற்றும்மருத்துவ வழிமுறை பற்றியும்,தொடர்ந்து எனது உடல் இயக்கத்தைக் கண்காணிக்கவும், அதனை பாதுகாக்கவும் பயன்படும்மருத்துவ ஆய்வுக்கூட பரிசோதனைகள் பற்றி திருப்தி அளிக்கும் வகையில்மருத்துவரால்விளக்கிக் கூறப்பட்டது.

நான் இந்த ஆய்வின் போது, காரணம் எதுவும்கூறாமல், எப்பொழுது வேண்டுமானாலும் இந்த ஆய்விலிருந்து என்னைவிடுவித்துக் கொள்ளும் உரிமைத் தெரிந்திருக்கிறேன். நான் என்னுடைய சுகந்திரமாக தேர்வு செய்யும் உரிமைக் கொண்டுமதுமேகம் என்னு நோய்க்கானமருதம்பட்டை சூரணம்(உள் மருந்து) மற்றும் யோகம் மருத்துவத்தின் பரிகரிப்பு திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கு என்னை உட்படுத்த ஒப்புதல் அளிக்கிறேன்.

தேதி: **கையொப்பம்:**

இடம்: **பெயர்:**

சாட்சிகாரர் கையொப்பம்:

பெயர்:

உறவுமுறை:

விரிவுரையாளர் கையொப்பம்: **துறைத்தலைவர் கையொப்பம்:**

NATIONAL INSTITUTE OF SIDDHA,
AYOTHIDASS PANDITHAR HOSPITAL CHENNAI 47,
DEPARTMENT OF SIRAPPU MARUTHUVAM

PRECLINICAL AND COMPARATIVE CLINICAL STUDY OF MARUTHAMPATTAI KUDINEER AND YOGAM THERAPY IN THE MANAGEMENT OF MADHUMEGAM (TYPE II DIABETES)

FORM VII- WITHDRAWAL FORM

IEC NO:

NAME: _____

OPD/ IPD NUMBER: _____

AGE: _____ SERIAL NO: _____

DATE OF TRIAL COMMENCEMENT:

DATE OF WITHDRAWAL FROM TRIAL:

REASONS FOR WITHDRAWAL:

Long absence at reporting:	Yes/ No
Irregular treatment:	Yes/ No
Shift of locality:	Yes/No
Increase in severity of symptoms:	Yes/No
Development of severe adverse drug reactions:	Yes/No

NATIONAL INSTITUTE OF SIDDHA,
AYOTHIDASS PANDITHAR HOSPITAL CHENNAI 47,
DEPARTMENT OF SIRAPPU MARUTHUVAM

PRECLINICAL AND COMPARATIVE CLINICAL STUDY OF MARUTHAMPATTAI KUDINEER AND YOGAM THERAPY IN THE MANAGEMENT OF MADHUMEGAM (TYPE II DIABETES)

Form VII B – ADVERSE REACTION FORM/ PHARMACOVIGILANCE FORM

1. S.l. No:	2. OP/ IP No :	3. Name:
4. Age:	5. Gender:	6. Date of Enrollment:
7. Date of completion:	8. Informant:	9. Reliability:

Name :

Age :

Gender :

OPD/ IPD No :

Registration No :

Date of trial commencement :

Date of withdrawal from trial :

Description of adverse reaction :

Date: **Signature of Investigator**

Signature of Guide

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.

DEPARTMENT OF SIRAPPU MARUTHUVAM

PRECLINICAL AND COMPARATIVE CLINICAL STUDY OF MARUTHAMPATTAI KUDINEER AND YOGAM THERAPY IN THE MANAGEMENT OF MADHUMEGAM (TYPE II DIABETES)

Principal Investigator: Dr. B. Vinubharathi

சேர்க்க கூடிய உணவுகள்:

காய்கள்:

முருங்கைபிஞ்சு,

அவரைபிஞ்சு,

பிரண்டை,

காரட்,

பீட்ரூட்.

கீரைகள்:

கரிசாலை,

பொன்னாங்கண்ணி,

மணத்தக்காளி,

முருங்கைகீரை,

பசலைகீரை,

சிறுகீரை,

கறிவேப்பிலை,

கொத்தமல்லி.

புதினா.

பழங்கள்:

மாதுளை,

ஆப்பிள்,

வாழை,

பேரீச்சை,

அத்தி,

திராட்சை,

கொய்யா

நாவல்,

சப்போட்டா,

உலர் திராட்சை.

தானியங்கள்

முளை கட்டிய பயிர் வகைகள்,

சோயாபீன்ஸ்,

வெந்தயம்.

அசைவம்:

வெள்ளாட்டுகறி ஈரல்,

எலும்புமஜ்ஜை,

மற்றவை:

பனை வெல்லம்

பால்

தவிர்க்க வேண்டியவைகள்:

கோழிக்கறி, மீன், நண்டு, கருவாடு,

வேர்க்கடலை,

எள்ளு,

பப்பாளி,

அன்னாசி,

நல்லெண்ணெய்,

புளிப்பு பொருள்கள்,

எலுமிச்சை,

தக்காளி,

ஊறுகாய்,

பெண்போகம், புகையிலை ,

வெற்றிலை,பாக்கு.

NATIONAL INSTITUTE OF SIDDHA- राष्ट्रीय सिद्ध संस्थान
Ministry of AYUSH- आयुष मंत्रालय
GOVERNMENT OF INDIA-भारत सरकार
TAMBARAM SANATORIUM, CHENNAI -600 047 -तांबरम सनटोरियमचेन्नई -600 047
फोन\Tele : 044-22411611
ईमेल: nischennaisiddha@yahoo.co.in
फैक्स\Fax : 22381314
वेब www.nischennai.org

F.No.NIS/6-20/IEC/15-16

Dt: 14.10.2016

CERTIFICATE

Address of Ethics Committee: National Institute of Siddha, Tambaram Sanatorium, Chennai-600047, Tamil Nadu, India	
Principal Investigator: Dr. B.Vinubharathi – I year, Dept.of Sirappu Maruthuvam	
Protocol Title:- Preclinical and Comparative Clinical study of Marutham Pattai Kudineer and Yogam therapy in the management of Madhumegam (Type II Diabetes Mellitus)	
Documents filed	1) Protocol, 2) Data Collection forms
Clinical trial Protocol (others – Specify)	**Yes-(M.D-Dissertation)**
Informed consent documents	**Yes**
Any other documents	-
Date of IEC approval & its number	**NIS/IEC/2016/11-09/ 14.10.2016**

We approve the trial to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study.

(Dr.V.Subramanian)
Chairman

V. Banumathi 14/10/16

(Prof.Dr.V.Banumathi)
Member Secretary

NATIONAL INSTITUTE OF SIDDHA ★ CHENNAI 600 047

Clinical Trial Details (PDF Generation Date :- Mon, 09 Jul 2018 06:03:38 GMT)

CTRI Number	CTRI/2018/04/013163 [Registered on: 11/04/2018] - **Trial Registered Retrospectively**
Last Modified On	03/04/2018
Post Graduate Thesis	Yes
Type of Trial	Interventional
Type of Study	Siddha
Study Design	Single Arm Trial
Public Title of Study	To study the effectiveness of yogam therapy in the management of diabetes mellittus
Scientific Title of Study	Preclinical and comparative clinical study of Maruthampattai kudineer and yogam therapy in the management of Madhumegam(Type II diabetes mellitus)

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Vinubharathi B
Designation	PG Scholar
Affiliation	National Institute of Siddha
Address	Ayothidass pandithar hospital, National Institute of Siddha, Tambaram sanatorium, Chennai. Kancheepuram TAMIL NADU 600047 India
Phone	9597274326
Fax	
Email	vinujuny21@gmail.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	N J Muthukumar
Designation	Associate Professor
Affiliation	National Institute of Siddha
Address	Ayothidass pandithar hospital, National Institute of Siddha, Tambaram sanatorium, Chennai. Kancheepuram TAMIL NADU 600047 India
Phone	9962006843
Fax	
Email	njmuthu@hotmail.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	N J Muthukumar
Designation	Associate Professor
Affiliation	National Institute of Siddha
Address	Ayothidass pandithar hospital, National Institute of Siddha, Tambaram sanatorium, Chennai. TAMIL NADU 600047 India
Phone	9962006843

Fax	
Email	njmuthu@hotmail.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> self

Primary Sponsor

Primary Sponsor Details	
Name	B Vinubharathi
Address	Ayothidass pandithar hospital, National Institute of Siddha, Tambaram sanatorium, Chennai.
Type of Sponsor	Research institution and hospital

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
B Vinubharathi	Sirappu maruthuvam OPD	Ayothidass pandithar hospital, National Institute of Siddha, Tambaram sanatorium, Chennai. Kancheepuram TAMIL NADU	9597274326 vinujuny21@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Ethical Committee	Approved	14/10/2016	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Patient with fasting blood sugar less than 150 mg/dl, post postprandial less than 250 mg/dl and Hba1c less than 6 to 8

Intervention / Comparator Agent

Type	Name	Details
Intervention	Maruthampattai Kudineer (internal medicine)	Maruthampattai kudineer is a polyherbal formulation in a dosage of 60 ml (b.d) for 90 days
Comparator Agent	Yogam therapy	Suriyanamaskaram Bavanamuthasanam Halasanam Pujagasanam vakrasanamam

Inclusion Criteria

Inclusion Criteria	
Age From	35.00 Year(s)
Age To	65.00 Year(s)
Gender	Both
Details	1. Symptoms of polyuria, polyphagia, nocturia, polydypsia. 2. Blood glucose level: fasting blood glucose- less than 150 mg/dl, postprandial level less than 250 mg/dl and Hba1c less 6 to 8. 3. Non insulin dependent diabetes mellitus.

Exclusion Criteria

Exclusion Criteria

Details	Blood glucose level: fasting blood glucose- less than 151 mg/dl, postprandial level greater than 250 mg/dl and Hba1c above 8.1 insulin dependent diabetes mellitus. patient with diabetic complication diabetic foot,retinopathy etc. any other serious systemic illness pregnancy and lactation

Method of Generating Random Sequence	Not Applicable
Method of Concealment	Not Applicable
Blinding/Masking	Not Applicable

Primary Outcome

Outcome	Timepoints
To observe the changes in the HbA1c	1 - 90 days

Secondary Outcome

Outcome	Timepoints
To observe the changes in fasting and postprandial blood glucose level	1-90 days

Target Sample Size	**Total Sample Size=**40 **Sample Size from India=**40
Phase of Trial	Phase 2
Date of First Enrollment (India)	28/12/2017
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**2 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Closed to Recruitment of Participants
Publication Details	nil
Brief Summary	

CERTIFICATE

This is certify that the project title Preclinical and Comparative clinical study of *Marutham pattai Kudineer* and *Yogam* In the Management of *Madhumegam* (Type-II Diabetes) **has been approved by the IAEC.**

Approval No: NIS/IAEC-III/11/29092016

Total No. of animals approved: 89 Rats (40M+49F)

Prof.Dr.V.Banumathi
Name of Chairman/Member Secretary IAEC:

Prof.Dr.K. Nachimuthu
Name of CPCSEA nominee:

Signature with date
V. Banumathi 17.11.16
Chairman/Member Secretary of IAEC:

29/11/2016
CPCSEA nominee:

(Kindly make sure that minutes of the meeting duly signed by all the participants are maintained by Office)

Name of the PI: Dr.B.Vinubharathi

Name of the Department: Sirappu Maruthuvam

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 600047

BOTANICAL CERTIFICATE

Certified that the following plant drugs used in the Siddha formulation **"Maruthampattai kudineer"** (Internal) taken up for Post Graduation Dissertation studies by **Dr.B.Vinubharathi** M.D.(S), II year, Department of Sirappu Maruthuvam, 2017, are identified through Visual inspection, Experience, Education & Training, Organoleptic characters, Morphology and Taxonomical methods as

Terminalia arjuna (DC) Wight & Arn. (Combretaceae), Stem Bark
Syzygium cumini Linn. (Myrtaceae), Stem Bark
Acacia senegal (L.) Willd. (Mimosaceae), Stem Bark
Ficus racemosa Linn. (Moraceae), Stem Bark
Cassia auriculata Linn. (Caesalpiniaceae), Stem Bark
Salacia reticulata Wight. (Celastraceae), Root Bark
Strychnos potatorum Linn. (Loganiaceae), Seed
Areca catechu Linn. (Arecaceae), Nut
Terminalia chebula Retz. (Combretaceae), Fruit
Terminalia belerica Roxb. (Combretaceae), Fruit

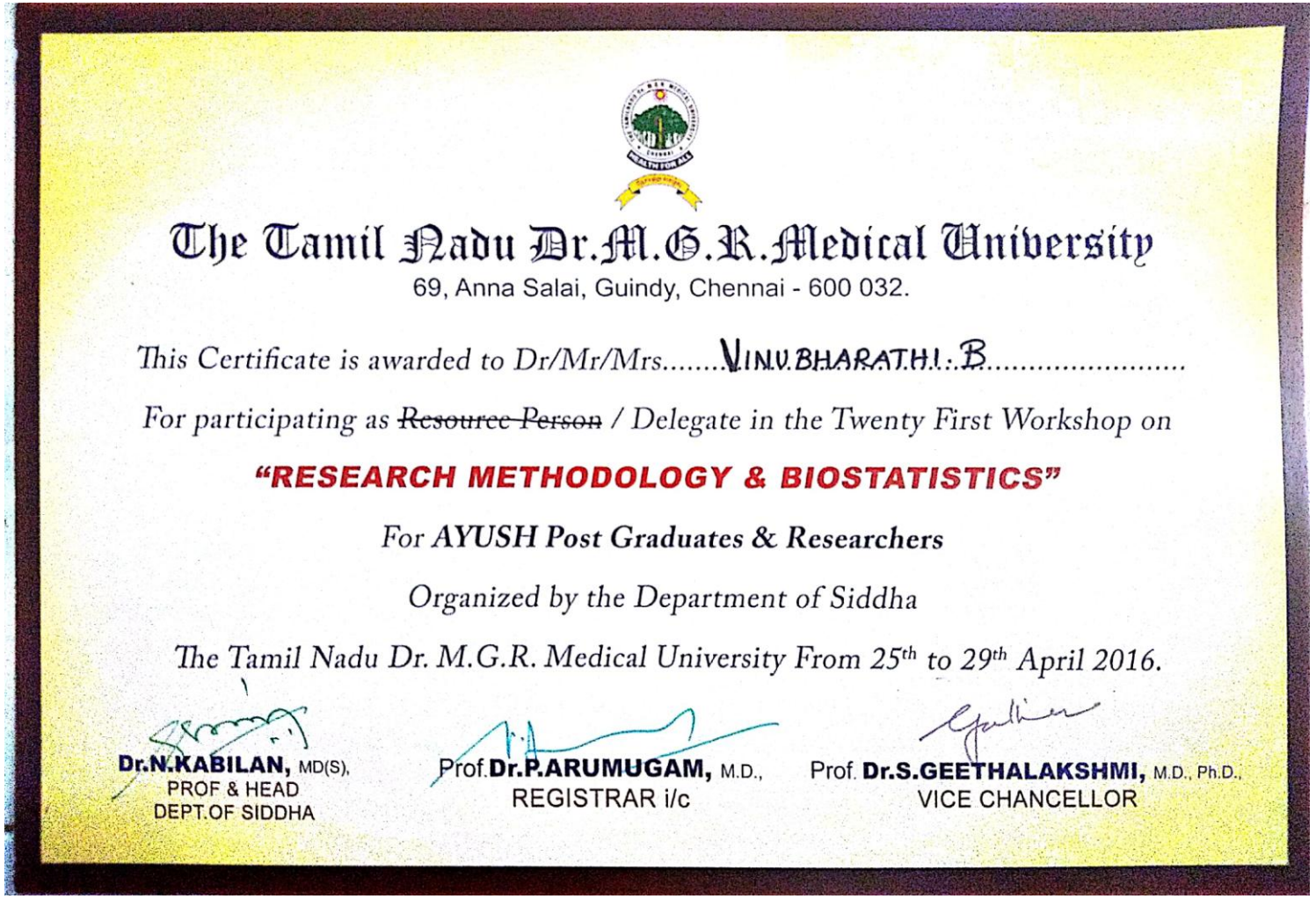
MEDICINAL BOTANY * CHENNAI 600 047 * National Institute of Siddha

Certificate No: NISMB2902017

Date: 23-3-17

Authorized Signatory

Dr. D. ARAVIND, M.D.(S),M.Sc.,
Assistant Professor
Department of Medicinal Botany
National Institute of Siddha
Chennai - 600 047, INDIA



The Tamil Nadu Dr.M.G.R.Medical University

69, Anna Salai, Guindy, Chennai - 600 032.

This Certificate is awarded to Dr/Mr/Mrs..... VINU.BHARATHI.B .....

For participating as ~~Resource Person~~ / Delegate in the Twenty First Workshop on

"RESEARCH METHODOLOGY & BIOSTATISTICS"

*For **AYUSH Post Graduates & Researchers***

Organized by the Department of Siddha

The Tamil Nadu Dr. M.G.R. Medical University From 25th to 29th April 2016.

Dr.N.KABILAN, MD(S),
PROF & HEAD
DEPT.OF SIDDHA

Prof.**Dr.P.ARUMUGAM,** M.D.,
REGISTRAR i/c

Prof. **Dr.S.GEETHALAKSHMI,** M.D., Ph.D.,
VICE CHANCELLOR

NATIONAL INSTITUTE OF SIDDHA

(An Autonomous body under Ministry of AYUSH, Govt. of India)
Tambaram Sanatorium, Chennai- 600 047

Workshop on

"BASIC RESEARCH TECHNIQUES AND PRACTICES INVOLVED IN LABORATORY ANIMAL CARE"

06 -10 February 2017

CERTIFICATE

This is to certify that Dr.....B.Vinubharathi..... has participated as Delegate/~~Resource~~ Person in the workshop on "Basic Research Techniques and Practices involved in Laboratory Animal Care" held on 06-10 February, 2017 at National Institute of Siddha, Chennai-47, Tamilnadu.

Dr. V. Suba
Organizing Secretary

Dr. P. Muthusamy
Veterinary Consultant

Prof. Dr. V. Banumathi
Director / Chairperson

National Conference on

Relevance of Sushruta's Concept of Surgery in Present Era

Shalyacon 2017

April 7-8, 2017

Organized by : **Department of Shalya Tantra,** Faculty of Ayurveda, Institute of Medical Sciences, Banaras Hindu University, Varanasi – 221005

In association with : **National Sushruta Association,** India

Certified that

Prof./Dr./Mr./Ms. B. Vinubharathi

has attended the conference as a **delegate.**

Prof. V. K. Shukla	Prof. M. Sahu	Prof. P. Mohan Kumar	Prof. Lakshman Singh	Dr. Shiv Ji Gupta
Director, IMS, BHU	Dean, Faculty of Ayurveda	President, NSA	Organizing Chairman	Organizing Secretary

தேசிய கருத்தரங்கம்

சித்த மருத்துவத்தில் புற மருத்துவ முறைகள்

SIDDHA REGIONAL RESEARCH INSTITUTE

(Under Central Council for Research in Siddha, Chennai.
Ministry of Ayush, Government of India)
Kuyavarpalayam, Puducherry - 605 013.

Certificate No : SRRI/NCPM/2017/405

Certificate

This is to certify that Dr./Sh./Km./Smt. **B. VINUBHARATHY**

has participated in the National Conference on Pura Maruthuvam - External Therapies in Siddha System of Medicine organized by Siddha Regional Research Institute, Puducherry, held on 9th & 10th December , 2017 at Dr. APJ Abdul kalam JIPMER Auditorium, Puducherry.

Organising Secretary **Convenor** **Chairman**